

# SOLICITATION

## SECTION A - SOLICITATION/CONTRACT FORM

1. Purchase Authority: Public Law 92-218 as amended		
<b>2. Request for Proposal (RFP) Number:</b>  N02CM91008-48	<b>3. Issue Date:</b>  October 1, 2008	<b>4. Set Aside:</b> <input type="checkbox"/> No <input checked="" type="checkbox"/> Yes Part IV Section L
5. Title : Operation and Support of the Cancer Therapy Evaluation Program's (CTEP's) Protocol and Information Office (PIO)		
<b>6. ISSUED BY:</b> Office of Acquisitions National Cancer Institute National Institutes of Health Executive Plaza South, Room 6062 6120 Executive Blvd., MSC 7193 Bethesda, MD 20892-7193  _____ _____	<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 3:00PM local time on October 31, 2008. 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 TO THE OFFICIAL POINT OF RECEIPT FOR THE PURPOSE OF DETERMINING TIMELY DELIVERY AS STATED IN ATTACHMENT 1, "PACKAGING AND DELIVERY OF THE PROPOSAL." IF YOUR PROPOSAL IS NOT RECEIVED BY THE CONTRACTING OFFICER OR HIS DESIGNEE AT THE PLACE AND TIME SPECIFIED, THEN IT WILL BE CONSIDERED LATE AND HANDLED IN ACCORDANCE WITH SUBPARAGRAPH (c)(3) OF FAR CLAUSE 52.215-1, ENTITLED, "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: John R. Manouelian PHONE: 301-435-3813 e-MAIL: manouelj@mail.nih.gov COLLECT CALLS WILL NOT BE ACCEPTED.		
All questions related to this solicitation are due by 3:00pm (local time) on October 15, 2008 and must be submitted via email to the Contracting Officer at the following e-Mail address: manouelj@mail.nih.gov .	John R. Manouelian Contracting Officer Office of Acquisitions National Cancer Institute	

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**NOTICE TO OFFERORS**

This solicitation is being processed under a Partnership Agreement (PA) between the Department of Health and Human Services (HHS) and the Small Business Administration (SBA), under which the SBA has delegated to HHS, authority to enter into 8(a) contracts directly with eligible 8(a) firms. The PA implements innovative and effective methodology designed to streamline the acquisition process for awards under the 8(a) program. The National Cancer Institute is a designated pilot agency under the PA.

Any solicitation and subsequent awards processed under the referenced PA, the National Cancer Institute will make the award directly to the 8(a) firm. SBA will not be a signatory to the award resulting from this solicitation. SBA will, however, retain responsibility for 8(a) certification, administer other eligibility related issues under the 8(a) program, and be available to 8(a) firms for counseling and assistance.

If you have any questions pertaining to this PA, please contact Annette Owens-Scarboro; 6100 Executive Blvd.; Rockville, MD 20892; 301-496-9639 .

**HHS/SBA PA 1 (March 20, 2007)**

**Servicing Small Business Administration Field Office**

To facilitate communications, it is requested that the 8(a) participant submitting this offer/bid provide the following information regarding the firm's cognizant servicing Small Business Administration (SBA) office.

Servicing SBA Office \_\_\_\_\_

Address \_\_\_\_\_

\_\_\_\_\_

Cognizant SBA Business Opportunity Specialist's Name \_\_\_\_\_

Phone \_\_\_\_\_

**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**

The Contractor shall staff, operate and maintain the Protocol and Information Office (PIO) of the National Cancer Institute's Cancer Therapy Evaluation Program (CTEP), Division of Cancer Treatment and Diagnosis (DCTD) on location in Bethesda, MD 20892.

**ARTICLE B.2. ESTIMATED COST PLUS AWARD FEE**

a. Estimated Cost and Base Fee

1. The total estimated cost of this contract is \$\_\_\_\_\_.
2. The total base fee (i.e. minimum fee payable hereunder) is \$\_\_\_\_\_.
  - a. The fee payment schedule will be determined during negotiations
  - b. Payment shall be subject to the withholding provision 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. Payment of fee shall not be made in less than monthly installments.

b. Award Fee Consideration

1. Based on the evaluation/determination described in subparagraph d. below, an award fee may be paid to the Contractor at regular intervals as defined in the paragraphs herein. The total potential award fee available is \$\_\_\_\_\_ and the evaluation periods shall be as follows:

Evaluation Period(s):	Available Award Fee:
Semi-annually	[To be negotiated]

c. Total Estimated Contract Amount

1. The total estimated amount of the contract, represented by the sum of the estimated cost plus the available award fee is \$\_\_\_\_\_.

2. Total funds currently available for payment and allotted to this contract are \$\_\_\_\_\_. Of which \$\_\_\_\_\_ represents the estimated costs, and of which \$\_\_\_\_\_ Represents the available award fee. For further provisions on funding, see the LIMITATION OF FUNDS clause referenced in Part II, ARTICLE I.2. Authorized Substitutions of Clauses.
3. It is estimated that the amount currently allotted will cover performance of the contract through \_\_\_\_\_.
4. The Contracting Officer may allot additional funds to the contract without the concurrence of the Contractor.

d. Methodology for Award Fee Evaluation/Determination

1. The Contractor's performance hereunder will be observed and evaluated continuously by the Government. At the end of each evaluation period, the Contracting Officer will review performance based on the standards and criteria established in the Quality Assurance Surveillance Plan, dated September 2008, provided as Appendix 5 to Attachment 3 - Statement of Work, listed in SECTION J - LIST OF ATTACHMENTS, attached hereto and made a part of this contract.
2. The findings of the evaluation will determine the amount of the available award fee (specified in subparagraph b. above) earned by the Contractor for the identified evaluation period. In no event, however, will any unearned award fee become available in subsequent evaluation periods.
3. The Contracting Officer will notify the Contractor, in writing, of the available award fee actually earned for a given evaluation period. Upon receipt of this notification, the Contractor may submit a public voucher for payment of the total award fee earned, less any previously billed partial payments authorized in subparagraph a. 2. (a) of this Article.
4. The evaluation/determination of award fee shall be binding on both parties and not subject to the Disputes clause included in Section I of the contract.

### **ARTICLE B.3. 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.4. 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 September 2008, 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 (1) hardcopy of each report shall be submitted to the Contracting Officer, unless otherwise specified.

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 versions, one hard copy of each report 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)

## **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, \_\_\_\_\_ is the authorized representative of the Contracting Officer.
- c. Inspection and acceptance will be performed at:  
The National Cancer Institute  
Bethesda, MD 20892

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

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 52.246-5, Inspection of Services - Cost-Reimbursement (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:

Item	Description	Quantity	Delivery Schedule
(1)	Monthly Progress Report	2	Due on or before the 15th calendar day following each monthly reporting period.
(2)	Final Progress Report	2	Due on or before the last day of the contract performance period.
(3)	Standard Operating Procedures (as per SOW, Section 5.9.1)	1	The SOPs shall be developed within 90 calendar days following the effective date of the contract and updated whenever business procedures are modified or as directed by the Project Officer.
(4)	Protocol Authoring Handbook Updates (as per SOW, Section 5.9.2)	1	The Contractor shall be responsible for updating the Protocol Authoring Handbook as directed by the Project Officer.
(5)	The Contractor shall provide any scheduled reports and conduct special inquiries of CTEP- ESYS (as per SOW, Section 5.9.4)	1	As directed by the Project Officer.
(6)	The Contractor shall develop presentations that communicate processes or results on activities to CTEP leadership (as per SOW, Section 5.9.5)	1	As directed by the Project Officer.
(7)	Quality Assurance Surveillance Plan (QASP) [as per SOW, Section 5.10.1]	1	Quarterly
(8)	The Contractor shall conduct two (2)	1	

Item	Description	Quantity	Delivery Schedule
	Satisfaction Surveys [one measuring satisfaction of CTEP personnel (including CTEP contractors) with PIO services, and the other measuring the satisfaction of customers that the PIO serves outside of CTEP personnel] (as per SOW, Section 5.11.1)		Annually, on or before the anniversary date of each contract year.
(9)	The Contractor shall conduct a minimum of four (4) training programs annually (as per SOW, Section 5.11.2)	1	Annually

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

Addressee	Deliverable Item No	Quantity
Project Officer	(1) - (9)	One
Contracting Officer	(1) and (2)	One

**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. PROJECT OFFICER**

The following Project Officer(s) will represent the Government for the purpose of this contract:

[To be specified prior to award]

The Project Officer 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 Project Officer designation.

**ARTICLE G.2. KEY PERSONNEL, HHSAR 352.270-5 (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
[To be specified prior to award]	

**ARTICLE G.3. 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  
 Office of Acquisitions  
 National Cancer Institute, NIH  
 EPS, Room 6062  
 6120 EXECUTIVE BLVD MSC 7193  
 BETHESDA, MD 20892- 7193

E-Mail: manouelj@mail.nih.gov

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, MSeXcel, 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 Subpart 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 E - ncibrancheinvoices@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/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/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 or contracts or orders held by an organization.

- b. Inquiries regarding payment of invoices shall be directed to the designated billing office, (301) - 496-6088.

#### **ARTICLE G.4. 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  
6100 Building, Room 6B05  
6100 EXECUTIVE BLVD MSC-7540  
BETHESDA MD 20892-7540

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

#### **ARTICLE G.5. 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, "Contractor's Guide for Control of Government Property," which can be found at:

<http://knownet.hhs.gov/log/AgencyPolicy/HHSLogPolicy/contractorsguide.htm>.

#### **ARTICLE G.6. 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 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) shall be prepared annually to coincide with the anniversary date of the contract.

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 that have Internet capability may access evaluations through a secure Web site for review and comment by completing the registration form that can be obtained at the following address:

<http://oamp.od.nih.gov/OD/CPS/cps.asp>

The registration process requires the Contractor to identify an individual that will serve as a primary contact and who will be authorized access to the evaluation for review and comment. In addition, the Contractor will be required to identify an alternate contact who will be responsible for notifying the cognizant contracting official in the event the primary contact is unavailable to process the evaluation within the required 30-day time frame.

## 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. NEEDLE EXCHANGE

Pursuant to the current HHS annual appropriations act, the Contractor shall not use contract funds to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

### ARTICLE H.3. PRESS RELEASES

Pursuant to the current HHS annual appropriations act, 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.4. RESTRICTION ON EMPLOYMENT OF UNAUTHORIZED ALIEN WORKERS

Pursuant to the current HHS annual appropriations act, 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.5. INFORMATION SECURITY

The Statement of Work (SOW) requires the Contractor to (1) develop, (2) have the ability to access, or (3) host and/or maintain a Federal information system(s). Pursuant to Federal and HHS Information Security Program Policies, the Contractor and any subcontractor performing under this contract shall comply with the following requirements:

Federal Information Security Management Act of 2002 (FISMA), Title III, E-Government Act of 2002, Pub. L. No. 107-347 (Dec. 17, 2002); <http://csrc.nist.gov/drivers/documents/FISMA-final.pdf>

a. Information Type

Administrative, Management and Support Information

Mission Based Information

b. Security Categories and Levels

Confidentiality Level:  Low  Moderate  High  
 Integrity Level:  Low  Moderate  High  
 Availability Level:  Low  Moderate  High

**Overall Level:**  **Low**  **Moderate**  **High**

c. Position Sensitivity Designations

1. The following position sensitivity designations and associated clearance and investigation requirements apply under this contract.

**Level 6: Public Trust - High Risk (Requires Suitability Determination with a BI).** Contractor employees assigned to a Level 6 position are subject to a Background Investigation (BI)

**Level 5: Public Trust - Moderate Risk (Requires Suitability Determination with NACIC, MBI or LBI).** Contractor employees assigned to a Level 5 position with no previous investigation and approval shall undergo a National Agency Check and Inquiry Investigation plus a Credit Check (NACIC), a Minimum Background Investigation (MBI), or a Limited Background Investigation (LBI).

**Level 1: Non Sensitive (Requires Suitability Determination with an NACI).** Contractor employees assigned to a Level 1 position are subject to a National Agency Check and Inquiry Investigation (NACI).

2. The Contractor shall submit a roster, by name, position, e-mail address, phone number and responsibility, of all staff (including subcontractor staff) working under the contract who will develop, have the ability to access, or host and/or maintain a Federal information system(s). The roster shall be submitted to the Project Officer, with a copy to the Contracting Officer, within 14 calendar days of the effective date of the contract. Any revisions to the roster as a result of staffing changes shall be submitted within 15 calendar days of the change. The Contracting Officer shall notify the Contractor of the appropriate level of suitability investigations to be performed. An electronic template, "Roster of Employees Requiring Suitability Investigations," is available for Contractor use at: <http://ais.nci.nih.gov/forms/Suitability-roster.xls>.

Upon receipt of the Government's notification of applicable Suitability Investigations required, the Contractor shall complete and submit the required forms within 30 days of the notification. Additional submission instructions can be found at the "NCI Information Technology Security Policies, Background Investigation Process" website: <http://ais.nci.nih.gov>.

Contractor/subcontractor employees who have met investigative requirements within the past five years may only require an updated or upgraded investigation.

3. Contractor/Subcontractor employees shall comply with the HHS criteria for the assigned position sensitivity designations prior to performing any work under this contract. The following exceptions apply:

Levels 5 and 1: Contractor/Subcontractor employees may begin work under the contract after the Contractor has submitted the name, position and responsibility of the employee to the Project Officer, as described in paragraph c. (2) above.

Level 6: In special circumstances the Project Officer may request a waiver of the pre-appointment investigation. If the waiver is granted, the Project Officer will provide written authorization for the Contractor/Subcontractor employee to work under the contract.

d. Information Security Training



The Contractor shall ensure that each Contractor/Subcontractor employee has completed the NIH Computer Security Awareness Training course at: <http://irtsectraining.nih.gov/> prior to performing any contract work, and thereafter completing the NIH-specified fiscal year refresher course during the period of performance of the contract.

The Contractor shall maintain a listing by name and title of each Contractor/Subcontractor employee working under this contract that has completed the NIH required training. Any additional security training completed by Contractor/Subcontractor staff shall be included on this listing. The listing of completed training shall be included in the first technical progress report. (See Article C.2. Reporting Requirements.) Any revisions to this listing as a result of staffing changes shall be submitted with next required technical progress report.

e. Rules of Behavior

The Contractor/Subcontractor employees shall comply with the NIH Information Technology General Rules of Behavior at: <http://irm.cit.nih.gov/security/nihitrob.html>.

f. Personnel Security Responsibilities

**Contractor Notification of New and Departing Employees Requiring Background Investigations**

1. The Contractor shall notify the Contracting Officer, the Project Officer, and the Security Investigation Reviewer **within five working days** before a new employee assumes a position that requires a suitability determination or when an employee with a security clearance stops working under the contract. The Government will initiate a background investigation on new employees requiring security clearances and will stop pending background investigations for employees that no longer work under the contract.
2. New employees: Provide the name, position title, e-mail address, and phone number of the new employee. Provide the name, position title and suitability level held by the former incumbent. If the employee is filling a new position, provide a description of the position and the Government will determine the appropriate security level.
3. Departing employees:
  - Provide the name, position title, and security clearance level held by or pending for the individual.
  - Perform and document the actions identified in the "Employee Separation Checklist", attached in Section J, ATTACHMENTS of this contract, when a Contractor/Subcontractor employee terminates work under this contract. All documentation shall be made available to the Project Officer and/or Contracting Officer upon request.

g. Commitment to Protect Non-Public Departmental Information Systems and Data

1. Contractor Agreement

The Contractor and its subcontractors performing under this SOW shall not release, publish, or disclose non-public Departmental information to unauthorized personnel, and shall protect such information in accordance with provisions of the following laws and any other pertinent laws and regulations governing the confidentiality of such information:

- 18 U.S.C. 641 (Criminal Code: Public Money, Property or Records)
- 18 U.S.C. 1905 (Criminal Code: Disclosure of Confidential Information)
- Public Law 96-511 (Paperwork Reduction Act)

2. Contractor-Employee Non-Disclosure Agreements

Each Contractor/Subcontractor employee who may have access to non-public Department information under this contract shall complete the Commitment to Protect Non-Public Information - Contractor

Agreement. A copy of each signed and witnessed Non-Disclosure agreement shall be submitted to the Project Officer prior to performing any work under the contract.

j. Common Security Configurations

The contractor shall ensure that any information technology acquired under this contract incorporates the applicable common security configuration established by the National Institute of Standards and Technology (NIST) at <http://checklists.nist.gov>.

## **ARTICLE H.6. STORAGE FACILITY REQUIREMENTS AND CERTIFICATION**

The Contractor shall ensure that all materials generated under this contract for which commercial records storage is required, shall be stored in a facility that meets National Archives and Records Administration (NARA) requirements for safe, secure and certified storage as required by 36 CFR 1228, subpart K.

The Contractor shall provide the Contracting Officer with the name(s) and location(s) of the commercial records storage facility used to store materials under this contract. In addition, the Contractor shall provide a copy of the "Facility Standards for Records Storage Facilities Inspection Checklist," self-certifying that the facility being used to store federal records meets established NARA standards. NARA Standards are available at: <http://www.archives.gov/about/regulations/part-1228/k.html>

Sixty (60) days prior to contract end date, the Contractor shall submit to the Project Officer and Contracting Officer, an inventory of all materials stored. The disposition of these materials shall be determined no later than the expiration date of the contract.

## **ARTICLE H.7. ELECTRONIC AND INFORMATION TECHNOLOGY ACCESSIBILITY (January 2008)**

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, and/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>.

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 order/contract exceeding \$100,000 when the order/contract 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 in the Product Assessment Template, remediation of the products and/or services to the level of conformance specified in the vendor's Product Assessment Template will be the responsibility of the Contractor at its own expense.

In the event of a modification(s) to the contract/order, which adds new EIT products and services or revised the type of, or specifications for, products and 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 and services support Section 508 accessibility requirements. Instructions for documenting accessibility via the HHS Section 508 Product Assessment Template may be found at <http://508.hhs.gov>.

[(End of HHSAR 352.270-19(b))]

Prior to the Contracting Officer exercising an option for a subsequent performance period/additional quantity or adding increment 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 Contracting Officer's Technical Representative (also known as Project Officer or Contracting Officer's Representative). 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 at: <http://508.hhs.gov/> 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 incremental funding, as applicable.

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

The Contractor shall submit the Section 508 Annual Report within 30 calendar days following the anniversary date of the contract, for each year of the contract, and shall submit the Final Section 508 Annual Report on the final day of contract performance.

[End of HHSAR 352.270-19(c)]

### **ARTICLE H.8. ACCESS TO NATIONAL INSTITUTES OF HEALTH (NIH) ELECTRONIC MAIL**

All Contractor staff that have access to and use of NIH electronic mail (e-mail) must identify themselves as contractors on all outgoing e-mail messages, including those that are sent in reply or are forwarded to another user. To best comply with this requirement, the Contractor staff shall set up an e-mail signature ("AutoSignature") or an electronic business card ("V-card") on each Contractor employee's computer system and/or Personal Digital Assistant (PDA) that will automatically display "Contractor" in the signature area of all e-mails sent.

### **ARTICLE H.9. CONFIDENTIALITY OF INFORMATION**

The following information is covered by **HHSAR 352.224-70, Confidentiality of Information** (January 2006):

1) Proprietary information contained in Investigational New Drug Applications (INDs) and reports to the Food and Drug Administration (FDA) containing such data; 2) proprietary data in NCI databases; 3) confidential information in all Adverse Event Reaction (AER) documentation; 4) all information regarding clinical trial protocols in the pre-approval stage; and 5) any protocol related proprietary data. Any dissemination of data relating to these documents and information shall be cleared through the Contracting Officer for the purpose of identifying any inadvertent disclosure of the data or information prior to any oral or written release of information. This includes abstracts, preprints and materials to be presented at conferences or in public forums. All information and materials handled by the Protocol and Information Office are considered proprietary and/or confidential data unless otherwise marked, including protocols which shall be totally confidential in the pre-approval stage.

### **ARTICLE H.10. 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.11. 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)

## **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>

#### **General Clauses for a Cost-Reimbursement Service 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 **52.219-9, Small Business Subcontracting Plan** (April 2008), and **52.219-16, Liquidated Damages--Subcontracting Plan** (January 1999) are deleted in their entirety.
- b. FAR Clause **52.232-20, Limitation Of Cost** (April 1984), is deleted in its entirety and FAR Clause **52.232-22, Limitation Of Funds** (April 1984) is substituted therefor. **[NOTE: When this contract is fully funded, FAR Clause 52.232-22, LIMITATION OF FUNDS will no longer apply and FAR Clause 52.232-20, LIMITATION OF COST will become applicable.]**

## ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES

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

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

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

1. FAR Clause **52.203-13, Contractor Code of Business Ethics and Conduct** (December 2007).
2. FAR Clause **52.203-14, Display of Hotline Poster(s)** (December 2007).

".....(3) Any required posters may be obtained as follows:

Poster(s)	Obtain From"
HHS Contractor Code of Ethics and Business Conduct Poster	<a href="http://www.oig.hhs.gov/hotline/OIG_Hotline_Poster.pdf">http://www.oig.hhs.gov/hotline/OIG_Hotline_Poster.pdf</a>

3. FAR Clause **52.204-9, Personal Identity Verification of Contractor Personnel** (September 2007).
4. FAR Clause **52.219-14, Limitations on Subcontracting** (December 1996).
5. FAR Clause **52.223-5, Pollution Prevention and Right-to-Know Information** (August 2003).
6. FAR Clause **52.223-10, Waste Reduction Program** (August 2000).
7. **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: None.
8. FAR Clause **52.237-2, Protection of Government Buildings, Equipment and Vegetation** (April 1984).
9. FAR Clause **52.242-3, Penalties for Unallowable Costs** (May 2001).
10. FAR Clause **52.246-23, Limitation of Liability** (February 1997).
11. FAR Clause **52.248-1, Value Engineering** (February 2000).

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

1. HHSAR Clause **352.224-70, Confidentiality of Information** (January 2006).

2. HHSAR Clause **352.270-13, Tobacco-Free Facilities** (January 2006).

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

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

1. **NIH (RC)-7, Procurement of Certain Equipment** (April 1984).



## 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 **52.219-28, Post-Award Small Business Program Representation** (June 2007).

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

*Long-term contract* means a contract of more than five years in duration, including options. However, the term does not include contracts that exceed five years in duration because the period of performance has been extended for a cumulative period not to exceed six months under the clause at 52.217-8, Option to Extend Services, or other appropriate authority.

*Small business concern* means a concern, including its affiliates, that is independently owned and operated, not dominant in the field of operation in which it is bidding on Government contracts, and qualified as a small business under the criteria in 13 CFR part 121 and the size standard in paragraph (c) of this clause.

(b) If the Contractor represented that it was a small business concern prior to award of this contract, the Contractor shall rerepresent its size status according to paragraph (e) of this clause or, if applicable, paragraph (g) of this clause, upon the occurrence of any of the following:

(1) Within 30 days after execution of a novation agreement or within 30 days after modification of the contract to include this clause, if the novation agreement was executed prior to inclusion of this clause in the contract.

(2) Within 30 days after a merger or acquisition that does not require a novation or within 30 days after modification of the contract to include this clause, if the merger or acquisition occurred prior to inclusion of this clause in the contract.

(3) For long-term contracts--

(i) Within 60 to 120 days prior to the end of the fifth year of the contract; and

(ii) Within 60 to 120 days prior to the exercise date specified in the contract for any option thereafter.

(c) The Contractor shall rerepresent its size status in accordance with the size standard in effect at the time of this rerepresentation that corresponds to the North American Industry Classification System (NAICS) code assigned to this contract. The small business size standard corresponding to this NAICS code can be found at <http://www.sba.gov/services/contractingopportunities/sizestandardsttopics/>.

(d) The small business size standard for a Contractor providing a product which it does not manufacture itself, for a contract other than a construction or service contract, is 500 employees.

(e) Except as provided in paragraph (g) of this clause, the Contractor shall make the rerepresentation required by paragraph (b) of this clause by validating or updating all its representations in the Online Representations and Certifications Application and its data in the Central Contractor Registration, as necessary, to ensure they reflect current status. The Contractor shall notify the contracting office by e-mail, or otherwise in writing, that the data have been validated or updated, and provide the date of the validation or update.

(f) If the Contractor represented that it was other than a small business concern prior to award of this contract, the Contractor may, but is not required to, take the actions required by paragraphs (e) or (g) of this clause.

(g) If the Contractor does not have representations and certifications in ORCA, or does not have a representation in ORCA for the NAICS code applicable to this contract, the Contractor is required to complete the following rerepresentation and submit it to the contracting office, along with the contract number and the date on which the rerepresentation was completed:

The Contractor represents that it [ ] is, [ ] is not a small business concern under NAICS Code assigned to contract number.

[Contractor to sign and date and insert authorized signer's name and title].

(End of clause)

b. FAR Clause **52.222-39, Notification Of Employee Rights Concerning Payment Of Union Dues Or Fees** (December 2004)

(a) *Definition. As used in this clause --*

*United States means the 50 States, the District of Columbia, Puerto Rico, the Northern Mariana Islands, American Samoa, Guam, the U.S. Virgin Islands, and Wake Island.*

(b) *Except as provided in paragraph (e) of this clause, during the term of this contract, the Contractor shall post a notice, in the form of a poster, informing employees of their rights concerning union membership and payment of union dues and fees, in conspicuous places in and about all its plants and offices, including all places where notices to employees are customarily posted. The notice shall include the following information (except that the information pertaining to National Labor Relations Board shall not be included in notices posted in the plants or offices of carriers subject to the Railway Labor Act, as amended (45 U.S.C. 151-188)).*

*Notice to Employees*

*Under Federal law, employees cannot be required to join a union or maintain membership in a union in order to retain their jobs. Under certain conditions, the law permits a union and an employer to enter into a union-security agreement requiring employees to pay uniform periodic dues and initiation fees. However, employees who are not union members can object to the use of their payments for certain purposes and can only be required to pay their share of union costs relating to collective bargaining, contract administration, and grievance adjustment.*

*If you do not want to pay that portion of dues or fees used to support activities not related to collective bargaining, contract administration, or grievance adjustment, you are entitled to an appropriate reduction in your payment. If you believe that you have been required to pay dues or fees used in part to support activities not related to collective bargaining, contract administration, or grievance adjustment, you may be entitled to a refund and to an appropriate reduction in future payments.*

*For further information concerning your rights, you may wish to contact the National Labor Relations Board (NLRB) either at one of its Regional offices or at the following address or toll free number:*

*National Labor Relations Board  
Division of Information  
1099 14th Street, N.W.  
Washington, DC 20570  
1-866-667-6572  
1-866-316-6572 (TTY)*

*To locate the nearest NLRB office, see NLRB's website at <http://www.nlr.gov>.*

(c) *The Contractor shall comply with all provisions of Executive Order 13201 of February 17, 2001, and related implementing regulations at 29 CFR part 470, and orders of the Secretary of Labor.*

(d) *In the event that the Contractor does not comply with any of the requirements set forth in paragraphs (b), (c), or (g), the Secretary may direct that this contract be cancelled, terminated, or suspended in whole or in part, and declare the Contractor ineligible for further Government contracts in accordance with procedures at 29 CFR part 470, Subpart B--Compliance Evaluations, Complaint Investigations and Enforcement Procedures. Such other sanctions or remedies may be imposed as are provided by 29 CFR part 470, which implements Executive Order 13201, or as are otherwise provided by law.*

(e) *The requirement to post the employee notice in paragraph (b) does not apply to--*

*(1) Contractors and subcontractors that employ fewer than 15 persons;*

*(2) Contractor establishments or construction work sites where no union has been formally recognized by the Contractor or certified as the exclusive bargaining representative of the Contractor's employees;*

*(3) Contractor establishments or construction work sites located in a jurisdiction named in the definition of the United States in which the law of that jurisdiction forbids enforcement of union-security agreements;*

*(4) Contractor facilities where upon the written request of the Contractor, the Department of Labor Deputy Assistant Secretary for Labor-Management Programs has waived the posting requirements with respect to any of the Contractor's facilities if the Deputy Assistant Secretary finds that the Contractor has demonstrated that--*

*(i) The facility is in all respects separate and distinct from activities of the Contractor related to the performance of a contract; and*

*(ii) Such a waiver will not interfere with or impede the effectuation of the Executive order;*  
*or*

*(5) Work outside the United States that does not involve the recruitment or employment of workers within the United States.*

(f) *The Department of Labor publishes the official employee notice in two variations; one for contractors covered by the Railway Labor Act and a second for all other contractors. The Contractor shall--*

*(1) Obtain the required employee notice poster from the Division of Interpretations and Standards, Office of Labor-Management Standards, U.S. Department of Labor, 200 Constitution Avenue, NW, Room N-5605, Washington, DC 2021, or from any field office of the Department's Office of Labor-Management Standards or Office of Federal Contract Compliance Programs;*

*(2) Download a copy of the poster from the Office of Labor-Management Standards website at <http://www.olms.dol.gov>; or*

*(3) Reproduce and use exact duplicate copies of the Department of Labor's official poster.*

(g) *The Contractor shall include the substance of this clause in every subcontract or purchase order that exceeds the simplified acquisition threshold, entered into in connection with this contract, unless exempted by the Department of Labor Deputy Assistant Secretary for Labor-Management Programs on account of special circumstances in the national interest under authority of 29 CFR 470.3(c).*

*For indefinite quantity subcontracts, the Contractor shall include the substance of this clause if the value of orders in any calendar year of the subcontract is expected to exceed the simplified acquisition threshold. Pursuant to 29 CFR part 470, Subpart B--Compliance Evaluations, Complaint*

*Investigations and Enforcement Procedures, the Secretary of Labor may direct the Contractor to take such action in the enforcement of these regulations, including the imposition of sanctions for noncompliance with respect to any such subcontract or purchase order. If the Contractor becomes involved in litigation with a subcontractor or vendor, or is threatened with such involvement, as a result of such direction, the Contractor may request the United States, through the Secretary of Labor, to enter into such litigation to protect the interests of the United States.*

*(End of Clause)*

Any contract resulting from this RFP will contain the following Article:

**ARTICLE I.5. SMALL BUSINESS ADMINISTRATION - 8(a) PROGRAM**

This contract has been awarded in accordance with the program established in Section 8(a) of the Small Business Act (15 U.S.C. 637(a)) and the Partnership Agreement (PA) between the U.S. Small Business Administration (SBA) and the U.S. Department of Health and Human Services (HHS) effective March 20, 2007. The following clauses are hereby incorporated and made a part of this contract. All clauses incorporated by reference have the same force and effect as if they were given full text. Upon request, the Contracting Officer will make their full text available.

**a. FAR Clause 52.219-18, Notification Of Competition Limited To Eligible 8(a) Concerns (June 2003) with Alternate For Acquisitions Under FAR 19.800 (Deviation) (HHS/SBA PA - March 20, 2007)**

(a) Offers are solicited only from (a) Offers are solicited only from small business concerns expressly certified by the Small business Administration (SBA) for participation in the SBA's 8(a) Program and which meet the following criteria at the time of submission of offer--

(1) The Offeror is in conformance with the 8(a) support limitation set forth in its approved business plan; and

(2) The Offeror is in conformance with the Business Activity Targets set forth in its approved business plan or any remedial action directed by the SBA.

(b) By submission of its offer, the Offeror represents that it meets all of the criteria set forth in paragraph (a) of this clause.

(c) Any award resulting from this solicitation will be made directly by the Contracting Officer to the successful 8(a) offeror selected through the evaluation criteria set forth in this solicitation.)

(d) Agreement.

(1) A small business concern submitting an offer in its own name shall furnish, in performing the contract, only end items manufactured or produced by small business concerns in the United States or its outlying areas. If this procurement is processed under simplified acquisition procedures and the total amount of this contract does not exceed \$25,000, a small business concern may furnish the product of any domestic firm. This subparagraph does not apply to construction or service contracts.

(2) The \_\_\_\_\_ [INSERT THE NAME OF SBA's CONTRACTOR] will notify the National Cancer Institute's Contracting Officer in writing immediately upon entering an agreement (either oral or written) to transfer all or part of its stock or other ownership interest to any other party.

## 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 (Non R & D)	<a href="#">Attachment_1_pd-nonrd.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="#">Attachment_3_Statement_of_Work.pdf</a>
Attachment 4:	Government Furnished Property	<a href="#">Attachment_4_Government_Furnished_Property.pdf</a>

#### TECHNICAL PROPOSAL ATTACHMENTS

Attachment No.	Title	Location
Attachment 5:	Summary of Related Activities	<a href="http://www.niaid.nih.gov/contract/forms.htm">http://www.niaid.nih.gov/contract/forms.htm</a>

#### BUSINESS PROPOSAL ATTACHMENTS

Attachment No.	Title	Location
Attachment 6:	Proposal Summary and Data Record, NIH-2043	<a href="http://www.niaid.nih.gov/contract/forms.htm">http://www.niaid.nih.gov/contract/forms.htm</a>
Attachment 7:	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 8:	Offeror's Points of Contact	<a href="http://www.niaid.nih.gov/contract/forms.htm">http://www.niaid.nih.gov/contract/forms.htm</a>
Attachment 9:	Certificate of Current Cost or Pricing Data	<a href="http://rcb.cancer.gov/rcb-internet/forms/cert-current-cost.pdf">http://rcb.cancer.gov/rcb-internet/forms/cert-current-cost.pdf</a>
Attachment 10:	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

Attachment No.	Title	Location
Attachment 11:	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 12:	Procurement of Certain Equipment, NIH(RC)-7	<a href="http://www.niaid.nih.gov/contract/forms/NIH-RC-7.pdf">http://www.niaid.nih.gov/contract/forms/NIH-RC-7.pdf</a>
Attachment 13:	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>
Attachment 14:	Commitment to Protect Non-Public Information Contractor Agreement	<a href="http://irm.cit.nih.gov/security/Nondisclosure.pdf">http://irm.cit.nih.gov/security/Nondisclosure.pdf</a>

<b>Attachment No.</b>	<b>Title</b>	<b>Location</b>
Attachment 15:	Roster of Employees Requiring Suitability Investigations	<a href="http://ais.nci.nih.gov/forms/Suitability-roster.xls">http://ais.nci.nih.gov/forms/Suitability-roster.xls</a>
Attachment 16:	Employee Separation Checklist	<a href="http://rcb.cancer.gov/rcb-internet/forms/Emp-sep-checklist.pdf">http://rcb.cancer.gov/rcb-internet/forms/Emp-sep-checklist.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 which can be accessed electronically from the INTERNET at the following address:  
<http://rcb.cancer.gov/rcb-internet/wkf/sectionk.pdf>

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



## 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, and 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, data contained in the portions of this proposal which have been specifically identified by page number, paragraph, etc. by the offeror as containing restricted information shall not be used or disclosed except for evaluation purposes.*

*The offeror acknowledges that the Department may not be able to withhold a record (data, document, etc.) nor deny access to a record requested pursuant to the Act and that the Department's FOI officials must make that determination. The offeror hereby agrees that the Government is not liable for disclosure if the Department 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. NOTICE OF 8(a) COMPETITIVE SET-ASIDE**

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

**c. 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 541990.
2. The small business size standard is \$6,500,000.

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

It is anticipated that one award will be made from this solicitation and that the award will be made on/about March 1, 2009.

It is anticipated that the award from this solicitation will be a multiple-year Cost-Reimbursement type Completion contract with a Period of Performance of seven (7) years, and that incremental funding will be used (See Section L.2.c. Business Proposal Instructions).

**e. PERFORMANCE BASED ACQUISITION**

The Government intends to use a Performance Based Acquisition method in the evaluation and award of any contract resulting from this RFP.

The Performance Based contract is designed to motivate the Contractor to perform at a higher standard. Outstanding performance is rewarded through an incentive defined in the contract. The following performance incentive will be used in any contract awarded from this RFP:

**Cost-Plus-Award-Fee (CPAF):** The CPAF contract includes an estimated cost and an award fee amount that is paid based upon periodic evaluations of Contractor performance. The Quality

Assurance Surveillance Plan (QASP), which is included as an attachment to this RFP sets forth all the elements required for evaluation and determination of the award fee amount. The award fee determination is made unilaterally by the Government and is not subject to Disputes clause procedures. The QASP is included in this RFP and located under SECTION J - LIST OF ATTACHMENTS.

**f. ESTIMATE OF EFFORT**

It is expected that a completion type contract will be awarded as a result of this RFP. To assist you in the preparation of your proposal, the Government considers the effort to be approximately 11,880 labor hours per year, for a total of 83,160 labor hours over the total seven (7) year period. This information is furnished for the offeror's information only and is not to be considered restrictive for proposal purposes.

**g. 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.

**h. 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.

**i. 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.

**j. REFERENCE MATERIALS**

The Cancer Therapy Evaluation Program (CTEP), DCTD, NCI maintains an active website (at <http://ctep.cancer.gov>) for use by CTEP and NCI staff, as well as the research and operations community that interacts with CTEP on the development of CTEP-sponsored trials. The website contains information that can be used to understand how, what and when a submitter needs to submit information to CTEP. Also included on the site are protocol templates that submitters can use, information about regulatory requirements, as well as information on other initiatives such as the Central Institutional Review Board (CIRB) and the Cancer Trails Support Unit (CTSU). Offerors responding to this solicitation are encouraged to view the entire website to gain an understanding of the scope of work that CTEP manages. Offerors may be particularly interested in, but not limited to, the following documents (at the respective urls provided) in preparing their proposal:

Investigator's Handbook: <http://ctep.cancer.gov/resources/index.html>

Protocol Authoring Handbook: <http://ctep.cancer.gov/guidelines/templates.html>

Treatment Assignment Codes Guidelines: <http://ctep.cancer.gov/guidelines/templates.html>

Amendment Submission Guidelines: <http://ctep.cancer.gov/guidelines/templates.html>

Clinical Data Update System Guidelines: <http://ctep.cancer.gov/resources/index.html>

PIO Standard Operating Procedures (SOPs): <http://ctep.cancer.gov/guidelines/artifacts.html>

CTEP-ESYS User Guides: <http://ctep.cancer.gov/guidelines/artifacts.html>

Failure of offerors to examine the above listed reference materials prior to proposal preparation and submission will be at the offeror's risk.

**k. PREPARATION COSTS**

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

**I. 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  
EPS, Room 6062  
6120 EXECUTIVE BLVD MSC 7193  
BETHESDA MD 20892- 7193

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

(End of Provision)

**2. INSTRUCTIONS TO OFFERORS**

**a. GENERAL INSTRUCTIONS**

**INTRODUCTION**

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

**1. Contract Type and General Clauses**

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

**2. Authorized Official and Submission of Proposal**

The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this RFP. Your proposal shall be submitted in the number of copies, to the addressees, and marked as indicated in the Attachment entitled,

PACKAGING AND DELIVERY OF PROPOSAL, Part III, Section J hereof. Proposals will be typewritten, paginated, reproduced on letter size paper and will be legible in all required copies. To expedite the proposal evaluation, all documents required for responding to the RFP should be placed in the following order:

**I. COVER PAGE**

Include RFP title, number, name of organization, 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 should disclose your technical approach in as much detail as possible, including, but not limited to, the requirements of the technical proposal instructions. The business 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 evaluation.

**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 technical proposals in accordance with the criteria 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 technical portion of each contract proposal will be evaluated by a technical review committee. The committee will evaluate each proposal in strict conformity with

the evaluation criteria of the RFP, utilizing point scores and written critiques. The committee may suggest that the Contracting Officer request clarifying information from an offeror.

- b. The business portion of each contract proposal will be subjected to a cost and price analysis, management analysis, etc.
- c. If award will be made without conducting discussions, offerors may be given the opportunity to clarify certain aspects of their proposal (e.g., the relevance of an offeror's past performance information and adverse past performance information to which the offeror has not previously had an opportunity to respond) or to resolve minor or clerical errors.
- d. If the Government intends to conduct discussions prior to awarding a contract -

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

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

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

While it is 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. Past Performance Information

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

A list of the last 10 contracts completed during the past Three 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 a subcontract in excess of \$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. 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 lack of a relevant past performance record may result in an unknown performance risk assessment, which will neither be used to the advantage or disadvantage to the offeror. The subfactors that will be used to evaluate the quality of the offeror's past performance (which are also provided under Section M, item 2. Technical Evaluation Criteria and item 3. Past Performance Factor) include the following: a) record of success in activities involving clinical trials, oncology and other biomedical fields; b) record of success in contracts with document management, data abstraction and data query activities; c) record of success in contracts providing operations support to health care providers (both internal and external to the client organization), at all levels of education and responsibility; and d) record of cost containment in providing services under a contract mechanism.

## 12. **Electronic and Information Technology Accessibility, HHSAR 352.270-19(a) (January 2008)**

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 Provisions (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:

1. 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
2. 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.

Accordingly, any vendor submitting a proposal/quotations/bid in response to this solicitation must demonstrate compliance with the established EIT accessibility provisions. 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>.

The Section 508 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 Assessment Template may be found at <http://508.hhs.gov>.

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 and/or services that are incidental to the project, which would constitute an exception to Section 508 requirements. If a vendor claims its products and/or services, including EIT deliverables such as electronic documents and reports, meet applicable Section 508 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 and/or services delivered do not conform to the described accessibility in the Product Assessment Template, remediation of the products and/or services to the level of conformance specified in the vendor's Product Assessment Template will be the responsibility of the Contractor at its expenses.

(End of provision)

**13. 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, (October 1997).*
- b. *Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8, (October 1997).*
- c. *Preaward On-Site Equal Opportunity Compliance Evaluation, (Over \$10,000,000), FAR Clause 52.222-24, (February 1999).*

**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. Personnel and Experience

Describe the experience, qualifications and availability of all personnel who will be assigned for direct work on this project. 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. Each area of the Statement of Work shall be addressed in sufficient detail to permit evaluation of the proposal, in terms of the adequacy and availability, as needed, of all staff to be assigned to the project. 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 and specifically to which tasks each employee would be assigned. Within the total estimated effort, offerors should indicate the specific estimate of effort which they consider appropriate for each function outlined in the Statement of Work. Please also provide a Personnel Ranking Matrix that indicates the hierarchical line of supervisory authority, which contractor employee(s) will perform the various tasks and the estimated percentage of time to be spent on each task.

Please provide complete, detailed resumes for all positions. Resumes should include educational background and related experience. In particular, experience with clinical trial protocol and related document, processes and data element databases should be included. Please include dates, places and names of previous employers, specific or technical accomplishments, and any related training.

**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. Project Management:

List the names of the individuals who shall be responsible for overall implementation and management of the contract. This includes the Program Manager, who shall be the offeror's key contact for technical aspects of the program, and those individuals also responsible for supervision and management of staff (i.e., the Deputy Program Manager and Senior Document Specialist(s)). Specifically, the Program Manager and Deputy Program Manager will be named as Key Personnel in the contract. Please discuss the qualifications, experience and accomplishments of the Project Management individuals. State the estimated time to be spent on the project, his/her/their proposed duties, and the areas or phases for which he/she will be responsible.

#### Program Manager:

In general, it is expected that the Program Manager shall possess relevant education and/or at least three years of management experience in the health care/clinical research fields. The CV of the individual should include all relevant education and any certifications earned. As the Program Manager shall be responsible for coordinating all Contractor activities pertaining to the work specified in the Statement of Work (SOW), this individual should demonstrate self-motivation, superior project and personnel management, effective communication, organization and process improvement skills. Specifically, he/she should demonstrate knowledge and experience in clinical trials development processes (both scientific and administrative); and knowledge and experience within the oncology

community. He/she should possess overall management capabilities, which would permit the effective implementation of all tasks on the project, including demonstrated experience in supervising all efforts of the type to be conducted under the contract, including managing teams of health care professionals at all levels. He/she should possess knowledge and experience with business improvement practices, which includes knowledge of quality control and quality assurance methods for all contract activities. He/she should demonstrate their experience in dealing with health care professionals at all levels, including effective use of both verbal and written communication skills and ability to provide successful presentations to those professionals, including orientation of new staff members. He/she should demonstrate experience with utilization of databases (including data element abstraction, milestone entry, generating queries and running canned reports), document management systems, the Internet and Microsoft Office software products, including experience with word processing and spreadsheet software. He/she should demonstrate their education and knowledge of medical terminology. He/she should demonstrate their knowledge and experience with the development and administration of survey tools.

Deputy Program Manager:

In general, it is expected that the Deputy Program Manager shall possess relevant education and/or management experience in the health care/clinical research fields. The CV of the individual should include all relevant education and any certifications earned. As the Deputy Program Manager shall be responsible for assisting the Program Manager--and serving in the Program Manager's capacity during the Program Manager's absence-- in the coordination of all Contractor activities pertaining to the work specified in the Statement of Work (SOW), this individual should demonstrate self-motivation, superior project and personnel management, effective communication, organization and process improvement skills. Specifically, he/she should demonstrate knowledge and experience in clinical trials development processes (both scientific and administrative aspects); and knowledge and experience within the oncology community. He/she should possess overall management capabilities, which would permit the effective implementation of all tasks on the project, including demonstrated experience in supervising all efforts of the type to be conducted under the contract, including managing teams of health care professionals at all levels. He/she should possess knowledge and experience with business improvement practices, which includes knowledge of quality control and quality assurance methods for all contract activities. He/she should demonstrate their experience in dealing with health care professionals at all levels, including effective use of both verbal and written communication skills and ability to provide successful presentations to those professionals, including orientation of new staff members. He/she should demonstrate experience with utilization of databases (including data element abstraction, milestone entry, generating queries and running canned reports), document management systems, the Internet and Microsoft Office software products, including experience with word processing and spreadsheet software. He/she should demonstrate their education and knowledge of medical terminology. He/she should demonstrate their knowledge and experience with the development and administration of survey tools.

Senior Document Specialist(s):

In general, it is expected that the Senior Document Specialist(s) shall possess relevant education and/or management experience in the health care/clinical research fields. The CV of the(se) individual(s) should include all relevant education and any certifications earned. As the Senior Document Specialist(s) shall be responsible for assisting the Program Manager and Deputy Program Manager in the coordination of all Contractor activities pertaining to the work specified in the Statement of Work (SOW), this/these individual(s) should demonstrate self-motivation, superior project and personnel management, effective communication, organization and process improvement skills. Specifically, he/she/they should demonstrate knowledge and experience in clinical trials development processes (both scientific and administrative aspects); and knowledge

and experience within the oncology community. He/she/they should possess overall management capabilities, which would permit the effective implementation of all tasks on the project, including demonstrated experience in supervising all efforts of the type to be conducted under the contract, including managing teams of health care professionals at all levels. He/she/they should possess knowledge and experience with business improvement practices, which includes knowledge of quality control and quality assurance methods for all contract activities. He/she/they should demonstrate their experience in dealing with health care professionals at all levels, including effective use of both verbal and written communication skills and ability to provide successful presentations to those professionals, including orientation of new staff members. He/she/they should demonstrate experience with utilization of databases (including data element abstraction, milestone entry, generating queries and running canned reports), document management systems, the Internet and Microsoft Office software products, including experience with word processing and spreadsheet software. He/she/they should demonstrate their education and knowledge of medical terminology. He/she/they should demonstrate their knowledge and experience with the development and administration of survey tools.

**2. Other Professional Support:**

**Document Specialists:**

List the names of all Document Specialists 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.

In general, it is expected that the Document Specialists shall possess relevant education and/or experience in the health care/clinical research fields. The CV of these individuals should include all relevant education and any certifications earned. As the Document Specialists shall be responsible for performing the activities pertaining to the work specified in the Statement of Work (SOW), these individuals should demonstrate self-motivation, effective communication, organization and process improvement skills. Specifically, they should demonstrate knowledge and experience in clinical trials development processes (both scientific and administrative aspects); and their education and knowledge of medical terminology. They should demonstrate their experience with utilization of databases, including data element abstraction, milestone entry, generation of queries and running of canned reports. In addition, they should demonstrate effective use of the Internet and Microsoft Office software products, including experience with word processing and spreadsheet software. They should demonstrate their experience in dealing with health care professionals at all levels, including effective use of both verbal and written communication skills and ability to assist in providing successful presentations to those professionals, including orientation of new staff members.

**3. Combined Range of Experience:**

The technical evaluation panel will evaluate the breadth and depth of the composite experience of the offeror's proposed team members with the tasks required by the Statement of Work to meet the protocol development needs of CTEP.

**4. Demonstrated Experience of Proposed Staff Working Together as a Team:**

The technical evaluation panel will evaluate the offeror's demonstrated experience of proposed staff working together as a team. Evidence of a stable workforce and the ability to recruit and retain staff will be considered.

**5. Demonstrated Availability of Personnel:**

The technical evaluation panel will evaluate the offeror's demonstrated availability of personnel proposed on the project.

**b. Adequacy of Technical Approach and Understanding of the Project**

a. 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.

b. Approach

The offeror must submit an explanation of the proposed technical approach in conjunction with the tasks to be performed and methods of quality assurance, in achieving the project objectives. The offeror should demonstrate a clear understanding of the potential problems involved with these types of projects. Proposals which merely restate the requirements of the Government's scope of work will not be eligible for award.

Specifically, the offeror should discuss its technical understanding of the requirements of the project, which includes: an understanding of the oncology community and cancer clinical research; an explanation of the methods and approach for accomplishing the tasks outlined in the Statement of Work, in a secure, flexible and user-friendly environment. The offeror should demonstrate their ability to meet with CTEP personnel on short or little notice. The offeror should discuss its plan for start-up of work under this contract. The offeror should discuss its understanding of Quality Assurance (QA) methods, goals and objectives. Specific descriptions of how the work performed will meet or exceed the Quality Assurance goals shall be addressed. Demonstration of approach to development of a QA plan, evaluation of activities covered in the QA plan, and methods used to update the QA plan, in accordance with the indicators measured in the QASP, shall be addressed. The offeror should discuss its plan to optimize data quality and timeliness of projects and tasks, as detailed in the Statement of Work. The offeror should discuss its ability to provide daily contact with CTEP staff, by the Program Manager, Deputy Program Manager and all other contract staff, as needed, to discuss and advise on the administrative and operational aspects of the protocol development process as it impacts CTEP operations and data abstraction processes. The offeror should discuss its experience with and ability to provide best business practices, regarding process improvement, continuous quality improvement principle and change management practices. The offeror should discuss its management plan which will provide the Project Officer with up-to-date financial information, project/subproject status and staffing information. The offeror should discuss its plan for providing annual training programs (including orientation of new personnel) to CTEP personnel, CTEP contractors or submitters and submitter personnel who interact with CTEP. The offeror should discuss its transition plan that would support a smooth transfer of responsibility for the project to a new Contractor upon completion of the contract.

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.

c. 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.

d. 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, as applicable, as well as for the overall program. Schedules shall be shown in terms of calendar months from the date of authorization to proceed or, where applicable, from the date of a stated event, as for example, receipt of a required approval by the Contracting Officer. Unless the request for proposal indicates that the stipulated schedules are mandatory, they shall be treated as desired or recommended schedules. In this event, proposals based upon the offeror's best alternative schedule, involving no overtime, extra shift or other premium, will be accepted for consideration.

## 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. **Information Security** 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, "INFORMATION SECURITY."**

The Federal Information Security Management Act of 2002 (P.L. 107-347) (FISMA) requires each agency to develop, document, and implement an agency-wide information security program to safeguard information and information systems that support the operations and assets of the agency, including those provided or managed by another agency, contractor (including subcontractor), or other source. The National Institute of Standards and Technology (NIST) has issued a number of publications that provide guidance in the establishment of minimum security controls for management, operational and technical safeguards needed to protect the confidentiality, integrity and availability of a Federal information system and its information.

The Statement of Work (SOW) requires the successful offeror to (1) develop, (2) have the ability to access, or (3) host and/or maintain a Federal information system(s). Pursuant to Federal and HHS Information Security Program Policies the following requirements apply to this solicitation:

Federal Information Security Management Act of 2002 (FISMA), Title III, E-Government Act of 2002, Pub. L. No. 107-347 (Dec. 17, 2002); <http://csrc.nist.gov/drivers/documents/FISMA-final.pdf>

- a. Information Type

Administrative, Management and Support Information:

C.3.5.6 Record Retention Information Type.

Mission Based Information:

D.19.1 Scientific Technical Research and Innovation Type.  
 D.21.3 Permits and Licensing Information Type.

b. Security Categories and Levels

Confidentiality Level:       Low  Moderate  High  
 Integrity Level:             Low  Moderate  High  
 Availability Level:         Low  Moderate  High  
**Overall Level:**             Low  Moderate  High

c. Position Sensitivity Designations

Prior to award, the Government will determine the position sensitivity designation for each Contractor (including subcontractor) employee that the successful offeror proposes for work under the contract. For proposal preparation purposes, the following designations apply:

**Level 6: Public Trust - High Risk (Requires Suitability Determination with a BI).** Contractor employees assigned to a Level 6 position are subject to a Background Investigation (BI).

**Level 5: Public Trust - Moderate Risk (Requires Suitability Determination with NACIC, MBI or LBI).** Contractor employees assigned to a Level 5 position with no previous investigation and approval shall undergo a National Agency Check and Inquiry Investigation plus a Credit Check (NACIC), a Minimum Background Investigation (MBI), or a Limited Background Investigation (LBI)

**Level 1: Non Sensitive (Requires Suitability Determination with an NACI).** Contractor employees assigned to a Level 1 position are subject to a National Agency Check and Inquiry Investigation (NACI).

Upon award, the Contractor will be required to submit a roster of all staff (including subcontractor staff) working under the contract who will develop, have the ability to access, or host and/or maintain a federal information system(s). The Government will determine and notify the Contractor of the appropriate level of suitability investigation required for each staff member. An electronic template, "Roster of Employees Requiring Suitability Investigations," is available for Contractor use at:  
<http://ais.nci.nih.gov/forms/Suitability-roster.xls>

Upon receipt of the Government's notification of applicable Suitability Investigations required, the Contractor shall complete and submit the required forms within 30 days of the notification. Additional submission instructions can be found at the "NCI Information Technology Security Policies, Background Investigation Process" website: <http://ais.nci.nih.gov>.

Contractor/Subcontractor employees who have met investigative requirements within the past five years may only require an updated or upgraded investigation.

d. Information Security Training

HHS policy requires Contractors/Subcontractors receive security training commensurate with their responsibilities for performing work under the terms and conditions of their contractual agreements.

The successful offeror will be responsible for assuring that each Contractor/Subcontractor employee has completed the NIH Computer Security Awareness Training course at: <http://irtsectraining.nih.gov/> prior to performing any contract work, and thereafter completing the NIH-specified fiscal year refresher course during the period of performance of the contract. The successful offeror shall maintain a listing of all individuals who have completed this training and shall submit this listing to the Project Officer.

Additional security training requirements commensurate with the position may be required as defined in NIST Special Publication 800-16, Information Technology Security Training Requirements ( <http://csrc.nist.gov/publications/nistpubs/800-16/800-16.pdf>). This document provides information about information security training that may be useful to potential offerors.

e. Offeror's Official Responsible for Information Security

The offeror shall include in the "Information Security" part of its Technical Proposal the name and title of its official who will be responsible for all information security requirements should the offeror be selected for an award.

f. Common Security Configurations

The contractor shall ensure that any information technology acquired under this contract incorporates the applicable common security configuration established by the National Institute of Standards and Technology (NIST) at <http://checklists.nist.gov>.

g. References

1. Federal Information Security Management Act of 2002 (FISMA), Title III, E-Government Act of 2002, Pub. L. No. 107-347 (Dec. 17, 2002); <http://csrc.nist.gov/drivers/documents/FISMA-final.pdf>
2. DHHS Personnel Security/Suitability Handbook: <http://www.hhs.gov/ohr/manual/pssh.pdf>
3. NIH Computer Security Awareness Training Course: <http://irtsectraining.nih.gov/>

The following NIST publications may be found at the following site: <http://csrc.nist.gov/publications/>

[Note: The search tool on the left side of this page provides easy access to the documents.]

4. NIST Special Publication 800-16, Information Technology Security Training Requirements; and Appendix A-D
5. NIST SP 800-18, Guide for Developing Security Plans for Information Technology Systems
6. NIST SP 800-26, Revision 1, Computer Security
7. NIST SP 800-53, Revision 1, Recommended Security Controls for Federal Information Systems
8. NIST SP 800-60, Guide for Mapping Types of Information and Information Systems to Security Categories, Volume I; and

Volume II, Appendices to Guide For Mapping Types of Information and Information Systems To Security Categories, Appendix C, and Appendix D

9. NIST SP 800-64, Security Considerations in the Information System Development Life Cycle
10. FIPS PUB 199, Standards for Security Categorization of Federal Information and Information Systems
11. FIPS PUB 200, Minimum Security Requirements for Federal Information and Information Systems

## 5. Uniform Assumptions

The following is a list of uniform assumptions to aid offerors in preparation of their proposal:

- Offerors should use the estimate that the PIO will handle approximately 2,000 protocol-related documents per year, which includes: Letters of Intent, Concepts, Protocols, Revisions, Amendments, IRB approvals, Case Report Forms.
- The Contractor should estimate that it will require approximately two (2) hours to completely abstract a Protocol and approximately one (1) hour to completely abstract an LOI, Concept, Revision and Amendment. This time includes data element abstraction, file preparation, processing comments and inquiries, and distribution of related correspondence.
- Appendix 3 of the Statement of Work contains a table with breakdown in volume by document type. In 2007, the incumbent Contractor distributed approximately 232 special mailings to investigators related to adverse events affecting approximately 5,500 protocols. The Contractor's effort per mailing is approximately one (1) hour. If a mailing results in an amendment to a protocol, the approximate additional time stated above is required to process the amendment.
- In 2007, the incumbent Contractor fulfilled approximately 50 typing requests made by CTEP personnel (typically, represents a request made by a lead reviewer to modify documentation that will be distributed to the submitter), requiring an average of 15 minutes per request.
- The Contractor shall prepare packets for weekly IDB, CRM and PRC meetings. It takes approximately three (3) hours weekly to prepare the IDB and CRM meeting packets and approximately four (4) hours to prepare the PRC meeting packet.
- The Contractor shall orient new staff to CTEP. Orientation lasts approximately one (1) hour. In 2007, the incumbent Contractor conducted approximately ten (10) such orientations.

## 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. Cost and Pricing Data

#### 1. General Instructions

- A. You must provide the following information 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 of contract administration office (if available);
  5. Type of contract action (that is, new contract, change order, price revision/redetermination, letter contract, unpriced order, or other);
  6. Proposed cost; profit or fee; and total;
  7. Whether you will require the use of Government property in the performance of the contract, and, if so, what property. See Item (13) Other Administrative Data, subparagraph (2) Government Property of this Section L.2.c of this solicitation.;
  8. Whether your organization is subject to cost accounting standards; whether your organization has submitted a CASB Disclosure Statement, and if it has been determined adequate; whether you have been notified that you are or may be in noncompliance with your Disclosure Statement or CAS, and, if yes, an explanation; whether any aspect of this proposal is inconsistent with your disclosed practices or applicable CAS, and, if so, an explanation; and whether the proposal is consistent with your established estimating and accounting principles and procedures and FAR Part 31, Cost Principles, and, if not, an explanation;
  9. The following statement: This proposal reflects our estimates and/or actual costs as of this date and conforms with the instructions in FAR 15.403 5(b)(1) and Table 15 2. By submitting this proposal, we grant the Contracting Officer and authorized representative(s) the right to examine, at any time before award, those records, which include books, documents, accounting procedures and practices, and other data, regardless of type and form or whether such supporting information is specifically referenced or included in the proposal as the basis for pricing, that will permit an adequate evaluation of the proposed price;
  10. Date of submission; and
  11. Name, title and signature of authorized representative.
- B. In submitting your proposal, you must include an index, appropriately referenced, of all the cost or pricing data and information accompanying or identified in the proposal. In addition, you must annotate any future additions and/or revisions, up to the date of agreement on price, or an earlier date agreed upon by the parties, on a supplemental index.
- C. As part of the specific information required, you must submit, with your proposal, cost or pricing data (that is, data that are verifiable and factual and otherwise as defined at FAR 15.401). You must clearly identify on your cover sheet that cost or pricing data are included as part of the proposal. In addition, you must submit with your proposal any information reasonably required to explain your estimating process, including
1. The judgmental factors applied and the mathematical or other methods used in the estimate, including those used in projecting from known data; and
  2. The nature and amount of any contingencies included in the proposed price.
- D. You must show the relationship between contract line item prices and the total contract price. You must attach cost element breakdowns for each proposed line item, using the appropriate format prescribed in the "Formats for Submission of Line Item Summaries" section of this table. You must furnish supporting breakdowns for each cost element, consistent with your cost accounting system.

- E. When more than one contract line item is proposed, you must also provide summary total amounts covering all line items for each element of cost.
- F. Whenever you have incurred costs for work performed before submission of a proposal, you must identify those costs in your cost/price proposal.
- G. If you have reached an agreement with Government representatives on use of forward pricing rates/factors, identify the agreement, include a copy, and describe its nature.
- H. As soon as practicable after final agreement on price or an earlier date agreed to by the parties, but before the award resulting from the proposal, you must, under the conditions stated in FAR 15.406 2, submit a Certificate of Current Cost or Pricing Data.

## 2. Cost Elements

Depending on your system, you must provide breakdowns for the following basic cost elements, as applicable:

- A. **Materials and services.** Provide a consolidated priced 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.). Include raw materials, parts, components, assemblies, and services to be produced or performed by others. For all items proposed, identify the item and show the source, quantity, and price. Conduct price analyses of all subcontractor proposals. Conduct cost analyses for all subcontracts when cost or pricing data are submitted by the subcontractor. Include these analyses as part of your own cost or pricing data submissions for subcontracts expected to exceed the appropriate threshold in FAR 15.403 4. Submit the subcontractor cost or pricing data as part of your own cost or pricing data as required in paragraph 2.A(2) of this table. These requirements also apply to all subcontractors if required to submit cost or pricing data.
  1. *Adequate Price Competition.* Provide data showing the degree of competition and the basis for establishing the source and reasonableness of price for those acquisitions (such as subcontracts, purchase orders, material order, etc.) exceeding, or expected to exceed, the appropriate threshold set forth at FAR 15.403 4 priced on the basis of adequate price competition. For interorganizational transfers priced at other than the cost of comparable competitive commercial work of the division, subsidiary, or affiliate of the contractor, explain the pricing method (see FAR 31.205 26(e)).
  2. *All Other.* Obtain cost or pricing data from prospective sources for those acquisitions (such as subcontracts, purchase orders, material order, etc.) exceeding the threshold set forth in FAR 15.403 4 and not otherwise exempt, in accordance with FAR 15.403 1(b) (i.e., adequate price competition, commercial items, prices set by law or regulation or waiver). Also provide data showing the basis for establishing source and reasonableness of price. In addition, provide a summary of your cost analysis and a copy of cost or pricing data submitted by the prospective source in support of each subcontract, or purchase order that is the lower of either \$11.5 million or more, or both more than the pertinent cost or pricing data threshold and more than 10 percent of the prime contractor's proposed price. The Contracting Officer may require you to submit cost or pricing data in support of proposals in lower amounts. Subcontractor cost or pricing data must be accurate, complete and current as of the date of final price agreement, or an earlier date agreed upon by the parties, given on the prime contractor's Certificate of Current Cost or Pricing Data. The prime contractor is responsible for updating a prospective subcontractor's data. For standard commercial items fabricated by the offeror that are generally stocked in inventory, provide a separate cost breakdown, if priced based on cost. For interorganizational transfers priced at cost, provide a separate breakdown of cost elements. Analyze the cost or pricing data and submit the results of your analysis of the prospective source's proposal. When submission of a prospective source's cost or pricing data is required

as described in this paragraph, it must be included along with your own cost or pricing data submission, as part of your own cost or pricing data. You must also submit any other cost or pricing data obtained from a subcontractor, either actually or by specific identification, along with the results of any analysis performed on that data.

- B. **Direct Labor.** Provide a time phased (e.g., monthly, quarterly, etc.) breakdown of labor hours, rates, and cost by appropriate category, and furnish bases for estimates.
- C. **Indirect Costs.** Indicate how you have computed and applied your indirect costs, including cost breakdowns. Show trends and budgetary data to provide a basis for evaluating the reasonableness of proposed rates. Indicate the rates used and provide an appropriate explanation.
- D. **Other Costs.** List all other costs not otherwise included in the categories described above (e.g., special tooling, travel, computer and consultant services, preservation, packaging and packing, spoilage and rework, and Federal excise tax on finished articles) and provide bases for pricing.
- E. **Royalties.** If royalties exceed \$1,500, you must provide the following information on a separate page for each separate royalty or license fee:
  - 1. Name and address of licensor.
  - 2. Date of license agreement.
  - 3. Patent numbers.
  - 4. Patent application serial numbers, or other basis on which the royalty is payable.
  - 5. Brief description (including any part or model numbers of each contract item or component on which the royalty is payable).
  - 6. Percentage or dollar rate of royalty per unit.
  - 7. Unit price of contract item.
  - 8. Number of units.
  - 9. Total dollar amount of royalties.
  - 10. If specifically requested by the Contracting Officer, a copy of the current license agreement and identification of applicable claims of specific patents (see FAR 27.204 and 31.205 37).
- F. **Facilities Capital Cost of Money.** When you elect to claim facilities capital cost of money as an allowable cost, you must submit Form CASB CMF and show the calculation of the proposed amount (see FAR 31.205 10).

### 3. **Formats for Submission of Line Item Summaries**

The detailed breakdown shall be in the format as shown on the form **Breakdown of Proposed Estimated Cost (plus fee) and Labor Hours** (Section J, List of Attachments). For each separate cost estimate, the offeror must furnish a breakdown by cost element as indicated above. In addition, summary total amounts shall be furnished. In the event the RFP cites specific line items, by number, a cost breakdown for each line item must be furnished.

### 4. **General Information**

- a. There is a clear distinction between submitting cost or pricing data and merely making available books, records, and other documents without identification. The requirement for submission of cost or pricing data is met when all accurate cost or pricing data reasonably available to the offeror have been submitted, either actually or by specific identification,

to the Contracting Officer or an authorized representative. As later information comes into your possession, it should be submitted promptly to the Contracting Officer in a manner that clearly shows how the information relates to the offeror's price proposal. The requirement for submission of cost or pricing data continues up to the time of agreement on price, or an earlier date agreed upon between the parties if applicable.

- b. By submitting your proposal, you grant the Contracting Officer or an authorized representative the right to examine records that formed the basis for the pricing proposal. That examination can take place at any time before award. It may include those books, records, documents, and other types of factual information (regardless of form or whether the information is specifically referenced or included in the proposal as the basis for pricing) that will permit an adequate evaluation of the proposed price.

**3. Requirements for Cost or Pricing Data or Information Other than Cost and Pricing Data [FAR Clause 52.215-20 (October 1997)]**

*(a) Exceptions from cost or pricing data.*

*(1) In lieu of submitting cost or pricing data, offerors may submit a written request for exception by submitting the information described in the following subparagraphs. The Contracting Officer may require additional supporting information, but only to the extent necessary to determine whether an exception should be granted, and whether the price is fair and reasonable.*

*(i) Identification of the law or regulation establishing the price offered. If the price is controlled under law by periodic rulings, reviews, or similar actions of a governmental body, attach a copy of the controlling document, unless it was previously submitted to the contracting office.*

*(ii) Commercial item exception. For a commercial item exception, the offeror shall submit, at a minimum, information on prices at which the same item or similar items have previously been sold in the commercial market that is adequate for evaluating the reasonableness of the price for this acquisition. Such information may include*

*(A) For catalog items, a copy of or identification of the catalog and its date, or the appropriate pages for the offered items, or a statement that the catalog is on file in the buying office to which the proposal is being submitted. Provide a copy or describe current discount policies and price lists (published or unpublished), e.g., wholesale, original equipment manufacturer, or reseller. Also explain the basis of each offered price and its relationship to the established catalog price, including how the proposed price relates to the price of recent sales in quantities similar to the proposed quantities;*

*(B) For market priced items, the source and date or period of the market quotation or other basis for market price, the base amount, and applicable discounts. In addition, describe the nature of the market;*

*(C) For items included on an active Federal Supply Service Multiple Award Schedule contract, proof that an exception has been granted for the schedule item.*

*(2) The offeror grants the Contracting Officer or an authorized representative the right to examine, at any time before award, books, records, documents, or other directly pertinent records to verify any request for an exception under this provision, and the reasonableness of price. For items priced using catalog or market prices, or law or regulation, access does not extend to cost or profit information or other data relevant solely to the offeror's determination of the prices to be offered in the catalog or marketplace.*



*(b) Requirements for cost or pricing data. If the offeror is not granted an exception from the requirement to submit cost or pricing data, the following applies:*

*(1) The offeror shall prepare and submit cost or pricing data and supporting attachments in accordance with Table 15.2 of FAR 15.408.*

*(2) As soon as practicable after agreement on price, but before contract award (except for unpriced actions such as letter contracts), the offeror shall submit a Certificate of Current Cost or Pricing Data, as prescribed by FAR 15.406 2.*

*(End of provision)*

**Alternate I** (October 1997) of FAR Clause **52.215-20, Requirements for Cost or Pricing Data or Information Other than Cost and Pricing Data** (October 1997). As prescribed in 15.408(I), **substitute the following paragraph (b)(1) for paragraph (b)(1) of the basic provision:**

*(b)(1) The offeror shall submit cost or pricing data and supporting attachments in the following format:*

*The format specified in paragraph L.2.c.(4) Cost and Pricing Data, subparagraph 3. Formats for Submission of Line Item Summaries shall be used for the submission cost information. Submission of all other cost or pricing data shall be in accordance with Table 15-2 in FAR 15.408.*

#### **4. 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).

**5. 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

A Listing of Government Furnished Property is provided in Section J - Solicitation Attachments of this solicitation

- 4. The management and control of any Government property shall be in accordance with the HHS Publication entitled, Contractors Guide for Control of Government Property, which can be found at: <http://knownet.hhs.gov/log/AgencyPolicy/HHSLogPolicy/contractorsguide.htm>

### 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. Incremental Funding**

An incrementally funded cost-reimbursement contract is a contract in which the total work effort is to be performed over a multiple year period and funds are allotted, as they become available, to cover discernible phases or increments of performance. The incremental funding technique allows for contracts to be awarded for periods in excess of one year even though the total estimated amount of funds expected to be obligated for the contract are not available at the time of the contract award. If this requirement is specified elsewhere in this RFP, the offeror shall submit a cost proposal for each year. In addition, the following provision is applicable:

**Incremental Funding, HHSAR 352.232-75 (January 2006)**

(a) It is the Government's intention to negotiate and award a contract using the incremental funding concepts described in the clause entitled Limitation of Funds as specified in FAR 52.232-22. Under the clause, which will be included in the resultant contract, initial funds will be obligated under the contract to cover the first year of performance. The Government intends to allot additional funds up to and including the full estimated cost of the contract for the remaining years of performance by contract modifications. However, the Government is not obligated to reimburse the Contractor for costs incurred in excess of the periodic allotments, nor is the Contractor obligated to perform in excess of the amount allotted.

(b) The Limitation of Funds clause to be included in the resultant contract, as specified in FAR 52.232-22, shall supersede the Limitation of Cost clause found in the Section I, Contract Clauses.

(End of provision)

**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.*

## 6. 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>

## 7. Proposer's Annual Financial Report

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

## 8. Representations and Certifications - SECTION K

One copy of SECTION K (which includes FAR Clause 52.204-8 Annual Representations and Certifications) shall be completed and be signed by an official authorized to bind your organization. Additionally, a completed copy of SECTION K shall be submitted from any proposed subcontractor. SECTION K can be found at: <http://rcb.cancer.gov/rcb-internet/wkf/sectionk.pdf>

## 9. 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.

## SECTION M - EVALUATION FACTORS FOR AWARD

### 1. GENERAL

Selection of an offeror for contract award will be based on an evaluation of proposals against three factors. The factors in order of importance are: technical, cost and past performance. Although technical factors are of paramount consideration in the award of the contract, both past performance and cost/price are also important to the overall contract award decision. Regarding the relative weighting of factors, technical evaluation factors are considered significantly more important than cost/price and past performance. However, in the event that the technical evaluation reveals that two or more offerors are approximately equal in technical ability, then cost/price and/or past performance may become significant factors in determining the award.

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

### 2. TECHNICAL EVALUATION CRITERIA

The evaluation criteria are used by the technical evaluation committee when reviewing the technical proposals. The criteria below are listed in the order of relative importance with weights assigned for evaluation purposes.

#### **A. Personnel and Experience = 50%**

*The below evaluation factors are listed in descending order of importance:*

#### 1. Qualifications of Project Management [Program Manager, Deputy Program Manager, Senior Document Specialist(s)]:

- Knowledge and experience in clinical trials development processes (both scientific and administrative aspects);
- Knowledge and experience within the oncology community;
- Demonstrated experience with managing teams of health care professionals at all levels;
- Knowledge and experience with business process improvement practices;
- Demonstrated experience in dealing with health care professionals at all levels;
- Demonstrated experience with utilization of databases (including data element abstraction, milestone entry, generating queries and running canned reports), document management systems, the Internet, and Microsoft Office products;
- Education and knowledge of medical terminology; and
- Knowledge and experience with the development and administration of survey tools.

#### 2. Qualification of Other Professional Support (Document Specialists):

- Knowledge and experience in clinical trials development processes (both scientific and administrative aspects);
- Education and knowledge of medical terminology;
- Demonstrated experience with databases, including: data element abstraction, milestone entry, generating queries and running canned reports; and
- Ability to communicate, both verbally and in writing, with health care professionals at all levels.

#### 3. Combined range of experience:

- Breadth and depth of composite experience of the proposed team members with the tasks required by the Statement of Work to meet the protocol development needs of CTEP;
- Composite experience of the proposed team members with protocol, document and process management activities; and
- Demonstration of ability to work with other contractors on projects.

4. Demonstrated experience of proposed staff working together as a team. Evidence of a stable workforce and the ability to recruit and retain staff.
5. Demonstrated availability of personnel.

**B. Adequacy of Technical Approach and Understanding of the Project = 30%**

*The below evaluation factors are listed in descending order of importance:*

1. Demonstration of an understanding of the needs of the project. Demonstration of an understanding of the oncology community and cancer clinical research. Explanation of the methods and approach for accomplishing the tasks outlined in the Statement of Work (Section 1 to 8) in a secure, flexible and user-friendly environment. Ability to meet with CTEP personnel on short notice.
2. Demonstrated understanding of Quality Assurance (QA) methods, goals and objectives. Specific descriptions of how the work performed will meet or exceed Quality Assurance goals shall be included. Demonstration of approach to development of a QA plan, evaluation of activities covered in the QA plan, and method used to update the QA plan in accordance with the indicators measured in the QASP.
3. Demonstrate a plan to optimize data quality and timeliness of projects and tasks as detailed in the Statement of Work and the QASP.
4. Demonstration of the ability to provide daily contact with CTEP staff by the Program Manager, Deputy Program Manager and other Contractor staff, as needed, to discuss and advise on the administrative and operational aspects of the protocol development process as it impacts CTEP operations and data abstraction processes.
5. Demonstrated experience with best business practices regarding process improvement, continuous quality improvement principle, and change management practices.
6. Demonstration of a management plan which will provide the Project Officer with up-to-date financial, project/subproject status and staffing information.
7. Plan for providing annual training programs (including orientation of new personnel) to CTEP personnel, CTEP contractors or submitters and submitter personnel who interact with CTEP.
8. Demonstration of a transition plan that would support a smooth transfer of responsibility for the project to a new Contractor upon completion of the contract.

**C. Past Performance = 20%**

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

*The past performance subfactors are listed below in descending order of importance. These subfactors will be used to evaluate the quality of past performance.*

- a. Record of success in activities involving clinical trials, oncology, and other biomedical fields;
- b. Record of success in contracts with document management, data abstraction, and data query activities;
- c. Record of success in contracts providing operations support to health care providers (both internal and external to the client organization), at all levels of education and responsibility; and
- d. Record of cost containment in providing services under a contract mechanism.

### **3. EVALUATION OF BUSINESS PROPOSAL**

A cost realism analysis will be conducted to determine whether the estimated proposed cost elements are realistic for the work to be performed; reflect a clear understanding of the requirements; and are consistent with the unique methods of performance and materials described in the offeror's technical proposal. Proposed costs will be evaluated for reasonableness, allowability, and allocability. This analysis is intended to determine the degree to which costs and fee included in the proposal are fair and reasonable.