

SOLICITATION

SECTION A - SOLICITATION/CONTRACT FORM

Page 1 of 69 pages

1. Purchase Authority: Public Law 92-218 as amended			
2. Request For Proposal (RFP) Number: N02-CN-65002-46	3. Issue Date: May 2, 2006	4. Just In Time <input checked="" type="checkbox"/> NO <input type="checkbox"/> YES See Part IV Section L	5. Set Aside: <input checked="" type="checkbox"/> NO <input type="checkbox"/> YES See Part IV Section L
6. TITLE: Cancer Prevention Clinical Trials Monitoring and Informatics Support			
7. ISSUED BY: Theresa H. Shroff Office of Acquisitions National Cancer Institute National Institutes of Health Executive Plaza South, Room 6008 6120 EXECUTIVE BLVD MSC 7195 BETHESDA MD 20892- 7195		8. SUBMIT OFFERS TO: See Part III, Section J, "Packaging and Delivery of the Proposal," ATTACHMENT 1 of this Solicitation.	
9. 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 until 3p.m. local time on June 2, 2006. 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."			
10. THIS SOLICITATION REQUIRES DELIVERY OF PROPOSALS TO THE OFFICIAL POINT OF RECEIPT FOR THE PURPOSE OF DETERMINING TIMELY DELIVERY AS STATED IN ATTACHMENT 1. 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.			
11. Offeror must be registered in the Central Contractor Registry (CCR) prior to award of a contract. (http://www.ccr.gov)			
12. FOR INFORMATION CALL: Elizabeth Dean PHONE: 301-435-3833 COLLECT CALLS WILL NOT BE ACCEPTED.			
13. Table of Contents on following page.			

Theresa Shroff
Contracting Officer
Office of Acquisitions
National Cancer Institute

13. DETAILED TABLE OF RFP CONTENTS

PART I - THE SCHEDULE

SECTION A - SOLICITATION/CONTRACT FORM 1
SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS 5
SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT 5
SECTION D - PACKAGING, MARKING AND SHIPPING 10
SECTION E - INSPECTION AND ACCEPTANCE 10
SECTION F - DELIVERIES OR PERFORMANCE 10
SECTION G - CONTRACT ADMINISTRATION DATA 13
SECTION H - SPECIAL CONTRACT REQUIREMENTS 15

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS 27
SECTION J - LIST OF ATTACHMENTS 27

PART IV - REPRESENTATIONS AND INSTRUCTIONS 29

SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS
..... 29
SECTION L - INSTRUCTIONS, CONDITIONS AND NOTICES TO OFFERORS 30
1. **GENERAL INFORMATION** 30
a. **INSTRUCTIONS TO OFFERORS--COMPETITIVE ACQUISITION** 30
b. **NAICS CODE AND SIZE STANDARD** 33
c. **TYPE OF CONTRACT AND NUMBER OF AWARDS** 34
d. **ESTIMATE OF EFFORT** 34
e. **COMMITMENT OF PUBLIC FUNDS** 34
f. **COMMUNICATIONS PRIOR TO CONTRACT AWARD** 34
g. **RELEASE OF INFORMATION** 34
h. **COMPARATIVE IMPORTANCE OF PROPOSALS** 34
i. **REFERENCE MATERIALS** 35
j. **PREPARATION COSTS** 35
k. **SERVICE OF PROTEST** 35
l. **AVAILABILITY OF THE "FEDERAL ADP AND TELECOMMUNICATIONS STANDARDS INDEX."** 35
2. **INSTRUCTIONS TO OFFERORS** 36
a. **GENERAL INSTRUCTIONS** 36
(1) **Contract Type and General Clauses** 36
(2) **Authorized Official and Submission of Proposal** 36
(3) **Proposal Summary and Data Record (NIH-2043)** 36
(4) **Separation of Technical and Business Proposals** 36
(5) **Alternate Proposals** 37
(6) **Evaluation of Proposals** 37
(7) **Potential Award Without Discussions** 37
(8) **Use of the Metric System of Measurement** 37
(9) **Standards for Privacy of Individually Identifiable Health Information** 37
(10) **Specific Copyright Provisions Applicable to Software Development and/or Enhancement(s)** 38
(11) **Privacy Act - Treatment of Proposal Information** 38
(12) **Selection of Offerors** 38
(13) **Institutional Responsibility Regarding Conflicting Interests of Investigators** .. 39
(14) **Past Performance Information** 41
(16) **Solicitation Provisions Incorporated by Reference,** 42
b. **TECHNICAL PROPOSAL INSTRUCTIONS** 43
(6) **Information Technology Systems Security** 49
c. **BUSINESS PROPOSAL INSTRUCTIONS** 52
(1) **Basic Cost/Price Information** 52
(2) **Cost and Pricing Data** 52
(3) **Small Business Subcontracting Plan** 55

(4)	HUBZone Small Business Concerns	57
(5)	Extent of Small Disadvantaged Business Participation	57
(6)	Total Compensation Plan - Instructions	59
(7)	Total Compensation Plan - Evaluation	59
(8)	Qualifications of the Offeror	60
(9)	Other Administrative Data	60
(10)	Subcontractors	62
(11)	Proposer's Annual Financial Report	63
(12)	Representations and Certifications	63
(13)	Travel Costs/Travel Policy	63
SECTION M - EVALUATION FACTORS FOR AWARD		64
a.	GENERAL	64
b.	TECHNICAL EVALUATION CRITERIA	64
c.	PAST PERFORMANCE FACTOR	65
d.	EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION	66
SOLICITATION ATTACHMENTS INCLUDED WITH THE RFP		67
PACKAGING AND DELIVERY OF THE PROPOSAL		68

PART I - THE SCHEDULE

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 PROPOSED CONTRACT DOCUMENT. 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. HOWEVER, THE ENCLOSED CONTRACT SCHEDULE PROVIDES ALL THE NECESSARY INFORMATION FOR THE OFFEROR 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 primary objectives of this acquisition are to provide monitoring and quality control auditing services for the Division of Cancer Prevention (DCP); to provide training regarding the conduct of cancer prevention trials to staff at clinical sites; and to provide on-going development, support and maintenance of the DCP central database, the DCP cancer prevention clinical trials database, and the mechanisms used to collect, analyze and report clinical trial data.

ARTICLE B.2. PRICES/COSTS

The final contract will contain the price/cost provisions agreed upon by the Government and the Offeror.

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 March 28, 2006, 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.

For proposal preparation purposes only, it is estimated that 2 copies of these reports will be required as follows:

(1) Monthly

The Contractor shall prepare and submit electronically a **monthly** progress report to the Project Officer(s). The initial report will be submitted for the first full month of the contract performance period, including any fractional part of the initial month. Thereafter, the reporting period shall consist of one full calendar month. The first report shall be due on xx, xx, 2007. A monthly report shall not be submitted when the annual progress report or final report is due.

Each monthly progress report shall be based on current project plans and shall include but not be limited to the following components:

Ongoing Projects

- A list of ongoing projects
- The status of each ongoing project
- The number of staff and staff titles for those who are working on each project
- Defined project role for each staff member working on a project
- Hourly rate for each staff member on the project
- Labor hours expended by each staff member on the project during the previous reporting period
- Total labor hours and dollars expended during the previous reporting period
- Anticipated total number of labor hours needed to complete the project
- Anticipated hours needed for the upcoming reporting period
- Overall budget projections for the upcoming reporting period
- Proposals for any project modifications for the upcoming reporting period
 - Rationale for project modifications
 - Amended timelines

Completed Projects

- A list of projects completed since the last reporting period
- The outcome of each completed project
- The number of staff and staff titles for those who have worked on each project
- Defined role for each staff member who has worked on the project
- Hourly rate for each staff member on the project
- Total labor hours expended by each staff member on the project.
- Total labor hours and dollars expended to complete the project

The reports also shall provide the information specified below:

Task 1:

- A description of any problems encountered with the submission of clinical trials data from the sites.
- Information on timeliness, completeness, and quality of data submitted.
- A brief listing and description of any special, non-routine reports produced for DCP from the database since the previous report.

Task 2:

- A site visit summary including the total number of sites visited, the names of the institutions visited and the names of the CRAs/CRCs conducting the visits, the types of visits conducted, and deficiencies found in initiation or auditing/monitoring visits since the previous report,
- A summary of institutions to be visited during the next 90 day period including total number of sites to be visited, the visit types, the names of the institutions to be visited and the names of the CRAs/CRCs who will be conducting the visits.
- A brief description of any changes in procedures for initiation visits or auditing/monitoring visits.

Task 3:

- A summary of any educational needs identified, materials and/or programs developed to meet those needs and measures used to evaluate the success of the educational materials or programs used.

Task 4:

- A summary of progress in the development, maintenance and integration of the clinical data transfer and reporting mechanisms of data from the clinical trials database (OC-RDC) and other specified data sources. .
- A summary of progress in the development of any required new systems and maintenance of existing systems and applications.
- A description of any general or specific problems encountered in meeting Task 4 requirements and recommendations for overcoming these problems.

(2) Annually

Each **annual** progress report shall include a summation of the results of all work performed during the period covered, including those components listed in the Monthly Progress report outlined above.

A monthly progress report need not be submitted on the month of the annual progress report review however, the information from the last month of the reporting period shall be incorporated into the annual progress report.

(3) Final - Upon final completion of the contract

This report is to include a summation of the work performed and results obtained for the entire contract period of performance. This report shall be in sufficient detail to comprehensively describe the results achieved. The Final Report shall be submitted **on the contract completion date**. An annual report will not be required for the period when the Final Report is due.

PROJECT PLANS AND REPORTS SUBMISSION REQUIREMENTS:

Monthly reports, annual reports, and annual project plan updates shall be presented to the Project Officer in a group meeting of Contract Task Leaders, the Contracting Officer (where applicable) and the Project Officer (s). Group meetings shall be scheduled by the Contractor staff and shall take place approximately **15 calendar days after the reporting period end date**. Project plans, monthly reports and annual reports shall be **electronically submitted 10 calendar days after the reporting period end date** for review by the Project Officer (s) and Contracting Officer.

DOCUMENTS, PROGRAMS, WORKING PAPERS, INFORMATION:

All data including source documents, case report forms, data files, databases, computer software, newly developed programs, system documentation, working papers, and all information collected, maintained and/or developed under this contract will be delivered to the Project Officer/Contracting Officer on the **contract end date or as specified by the Contracting Officer**.

b. Other Reports/Deliverables

1. Source Code and Object Code

Unless otherwise specified herein, the Contractor shall deliver to the Government, upon the expiration date of the contract, all source code and object code developed, modified, and/or enhanced under this contract.

2. Initial Overall Project Plan and Task Specific Project Plans

The initial overall project plan and task specific project plans shall include the following:

- Key project activities including but not limited to:
 - ▶ Reporting and communicating pertinent clinical trial information to DCP staff and other users specified by DCP
 - ▶ Developing metrics to evaluate clinical trial site performance in the areas of recruitment and retention, data quality and timeliness of data submissions
 - ▶ Reporting and communicating the outcome of all monitoring and quality control auditing visits
- Timelines for completion of project activities
- Budgets for the overall project plan and for each task specific project plan including:
 - ▶ Staff type or title
 - ▶ The number of staff with a given title working on the project
 - ▶ Staff role on the project
 - ▶ Hourly rate for each staff member on the project
 - ▶ Anticipated number of labor hours required for each staff member on the project
 - ▶ Anticipated number of labor hours to complete the project
- Methodology for:
 - ▶ Integrating each task to meet the overall project goals
 - ▶ Tracking and managing project timelines
 - ▶ Assuring that project plans are in compliance with applicable regulatory requirements

3. Annual Overall Project Plan and Task Specific Project Plans

The contractor shall present annually, an updated overall project plan and task specific project plans based on the accomplishments of the prior year and the goals and objectives for the remainder of the contract. The Project Plans shall include justification for any suggested changes to the plan, budgetary adjustments (as outlined in #2 above) and project timeline modifications.

4. Ad Hoc Project Plans

The ad hoc updates to the project plans shall be electronically submitted to the Project Officers within 21 calendar days of the Project Officer's request for additional support. DCP may review the "ad hoc" project plan(s) via email or may request a group meeting with Contractor staff.

*Any task that is anticipated to take more than 40 hours of labor to complete must be reviewed by the Project Officer (s) prior to implementation to determine if a project plan is needed. All project plans must be reviewed and approved by the Project Officer (s) prior to implementation

5. Site Visit Reports

All site visit reports are due to the Project Officer (s): Electronic Preliminary site visit reports due within 24 hours of a site visit and Final Site visit reports due within 15 calendar days of a site visit. The Contractor shall submit proposed templates for the various site reports to the Project Officer (s) for approval within the first 30 days of the effective date of the contract.

6. DCP Manual of Standard Operating Procedures

DCP Manual of Standard Operating Procedures for the Conduct of Cancer prevention Trials: revised every 6 months and as directed by the Project Officer(s).

7. DCP Web-Based Clinical Trials Resource

In collaboration with DCP staff, update the DCP web-based Clinical Trials Resource every 6 months and as directed by the Project Officer(s).

8. DCP Site coordinators' Meeting Presentations

In collaboration with DCP staff, the Contractor shall provide monitoring/auditing educational presentations and assistance with the education table and other tasks as directed by the Project Officer (s) for the annual DCP site coordinators' meeting.

9. Database Technical Documentation for the DCP instance of OC-RDC and DESK
Database technical documentation: Due within 30 days of system implementation. Documentation should include the data model, entity relationships, valid values, and domain and attribute definitions, and business rules. The document shall be updated as appropriate to reflect system changes.

In the event that the Project Officer (s) determine a new system or new instance of Oracle® Clinical is needed, the Contractor shall provide a transition plan which describes the testing procedures and validation according to CMMI level 3 or equivalent requirements. The plan shall be due to DCP POs 45 days prior to transition date. The Contractor shall assure that all recipient fields in the new clinical trials database match those in the existing system and that test data have been exchanged successfully with no errors in transmission. If a new system or new instance of Oracle® Clinical is needed, the Contractor shall monitor the quality of data and data transmissions during the first two months of transition, and shall provide the Project Officer (s) with data quality metrics such as but not limited to number of data discrepancies, transmission failures, and a reporting of Help Desk calls regarding technical and other difficulties encountered by end-users of the system. The Contractor shall provide a plan for 100% resolution of these issues and demonstrate that resolution has been attained. The Report of Data Quality Metrics and Plan for 100% Resolution of data discrepancies, transmission failures and any other difficulties shall be submitted to DCP POs 90 days after the transition date. The Project Officer will evaluate this plan and resolution and decide if final deployment of the new system shall proceed. As part of the transition plan, the Contractor shall propose alternate solutions should the new clinical trials database be disapproved by DCP.

10. Back-Up System for All Informatics Systems
The Contractor shall assure that all DCP electronic operations systems are backed up routinely. All systems shall be fully functional (daytime) 8 am – 8 pm Eastern Standard Time (E.S.T.), 7 days a week, 98% of the time. From (nighttime) 8 pm – 8 am E.S.T., the systems shall be operational 90% of the time, with the exception of weekends when a lower rate (not less than 80%) is acceptable. A demonstrable back-up system for all informatics systems is due within 30 days of the contract award date.
11. Disaster Recovery Plan
In the event of a major natural or man-made disaster, the down time for all systems developed to collect participant level data and for the personnel needed to operate the system shall not exceed 24 hours. Plans to achieve this recovery goal, (e.g., separate physical locations for operation of the systems used to collect participant level data), shall be incorporated into the organizational structure proposed by the Contractor and is a contract deliverable due within 30 days of the contract award date.
12. Database Participant Level Clinical Documentation
Database participant level clinical documentation: Ad hoc
13. Protocol Status Report
A standardized, monthly report to the Project Officers detailing clinical trial parameters as defined by the Project Officer (i.e., NCI study number, study name, institution name, PI name, study status, IND holder, sample size, participant accrual, regulatory issues).
14. Earned Value Management (EVM) Reports
EVM reports: due within the first 10 days of every month and as specified by DCP.
This is a monthly report documenting the progress of projects and activities related to the development, modification and/or enhancement of DCP's central database (DESK), and is used to measure cost and schedule performance of specifies IT components of a contract.
15. Plan for Transition from Existing Contract

The Contractor, Project Officer, and key NCI staff will establish a schedule with appropriate priority level assigned to each task during the entire phase-in period. Completion of the transition period should take place within the first three months of the contract period. The plan shall be due to DCP within 14 days of the contract award date.

16. Plan for Transition to Successor Contract

Prior to completion of this contract, the Contractor, in conjunction with the Project Officers, shall establish a plan for transfer of contractual activities and products to a successor contract. During the transition period, if required, the Contractor shall turn over contract material, files, documents, and any other holding to any organization or group selected by NCI/DCP as well as provide continuity of service during the transition period if a transfer is necessary. The Contractor shall provide any other assistance deemed reasonable by NCI/DCP that may be required for the smooth transfer of contract responsibility. The Contractor shall transfer newly developed programs, system documentation, working papers, and all information gathered during this contract to any entity selected as a result of recompetition of this project. The plan shall be due to DCP 45 days prior to contract end date.

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, the Project Officer is the authorized representative of the Contracting Officer.
- c. Inspection and acceptance will be performed at Department of Cancer Prevention, National Cancer Institute, 6130 Executive Boulevard, Room 2102, 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 Article C.1. 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 SECTION C, ARTICLE C.2. and SECTION H, ARTICLE H.5. will be required to be delivered F.o.b. Destination as set forth in FAR Clause 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)	Signed, Witnessed Non-Disclosure Agreements for each Contract employee who has access to sensitive information on this project	1 to Project Officer (PO) from each contract employee for whom this applies	Prior to commencement of work under this project
(2)	Contractor IT Staff Roster	4 electronic copies	Within 14 days of the contract award date and updated as needed
(3)	Transition Plan outlining the transition from the existing project	4 electronic copies	Within 14 days of the contract award date
(4)	Site Visit Report Templates	1 electronic copy	Within 30 days of the contract award date
(5)	Demonstrable back-up system for all informatics systems	1 electronic copy	Within 30 days of the contract award date
(6)	Disaster Recovery Plan	1 electronic copy	Within 30 days of the contract award date
(7)	Database Technical Documentation	4 electronic copies	Within 30 days of system implementation and updated as specified by PO
(8)	Initial Overall Project Plan	4 electronic copies	Within 60 calendar days of the contract award date
(9)	Initial Task Specific Project Plans	4 electronic copies	Within 60 calendar days of the contract award date
(10)	Security System Plan	1 electronic copy	Within 90 calendar days of the contract award date
(11)	Monthly Progress Reports	5 electronic copies	Within 10 calendar days following the month being reported
(12)	Protocol Status Report	electronic copies to multiple recipients	Within 10 calendar days following the month being reported
(13)	EVM Reports	4 electronic copies	Within the first 10 calendar days of each month
(14)	DCP Manual of Standard Operating Procedures	4 electronic copies	Every 6 months and as directed by DCP
(15)	DCP Web-Based Clinical Trials Resource	N/A	Every 6 months and as directed by DCP
(16)	Annual Overall Project Plan	4 electronic copies	Within 30 days following the contract year being reported
(17)	Annual Task Specific Project Plans	4 electronic copies	Within 30 days following the contract year being reported

(18)	Annual Progress Reports	5 electronic copies	Within 30 days following the contract year being reported
(19)	Monitoring/Auditing Educational Presentations and Assistance with Education Table and Other Tasks as Specified by DCP for Annual DCP Coordinators' Meeting	N/A	Within 30 days following the contract year being reported
(20)	Ad Hoc Project Plans	4 electronic copies	As Requested by the Project Officer
(21)	Database Participant Level Clinical Documentation	As Directed by PO	As Requested by the Project Officer
(22)	Final Report	5 electronic copies	Contract Completion Date
(23)	Preliminary Site Visit Report for each Site Visit	electronic copies to multiple recipients	Within 24 hours of Site Visit
(24)	Final Site Visit Report for each Site Visit	electronic copies to multiple recipients	Within 15 calendar days of the Site Visit
(25)	Transition Plan describing testing procedures and validation according to CMMI level 3 or equivalent requirements	1 electronic copy	45 days prior to system transition date
(26)	Report of data quality metrics: Data quality and data transmissions during the first two months of transition	1 electronic copy	90 days after the system transition date
(27)	Plan for 100% resolution of data discrepancies, transmission failures and any other difficulties	1 electronic copy	90 days after the system transition date
(28)	Transition Plan to successor contract	1 electronic copy	45 days prior to contract end date
(29)	Documents, Programs, Working Papers, Information	N/A	Contract Completion Date or as specified by DCP

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

Addressee	Deliverable Item No.	Quantity
-----------	----------------------	----------

[The specific information will be included in the resultant contract]

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

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. Also, the full text of a clause may be accessed electronically at this address: <http://www.arnet.gov/far/>.

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

Any contract resulting from this RFP will contain the following:

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 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

Pursuant to the Key Personnel clause incorporated in this contract, 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 instructions and the following directions for the submission of invoices/financing request must be followed to meet the requirements of a "proper" payment request pursuant to FAR 32.9.

These instructions also provide for the submission of financial and personnel reporting required by HHSAR 342.7002.

- (1) Invoices/financing requests shall be submitted as follows:
- (a) To be considered a "proper" invoice in accordance with FAR 32.9, Prompt Payment, each invoice shall clearly identify the two contract numbers that appear on the face page of the contract as follows:

Contract No. (This is the 17 digit number that appears in Block 2 of the SF-26, i.e. HHSN261200411000C.)

ADB Contract No. (This is the 10 digit number that appears in the upper left hand corner of the SF-26, i.e. N01-CO-41234.)

- (b) An original and two copies to the following designated billing office:

Contracting Officer
Office of Acquisitions
National Cancer Institute, NIH
EPS, Suite 600
6120 EXECUTIVE BLVD MSC 7195
BETHESDA MD 20892-7195

- (2) Inquiries regarding payment of invoices should be directed to the designated billing office.

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 DHHS Publication (OS) 686, 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 evaluations will 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

a. Pursuant to Public Law(s) cited in paragraph b., below, contract funds shall not be used to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

b.	Public Law and Section No.	Fiscal Year	Period Covered
----	-----------------------------------	--------------------	-----------------------

[Applicable information to be included at award]

ARTICLE H.3. PRIVACY ACT

This procurement action requires the Contractor to do one or more of the following: design, develop, or operate a system of records on individuals to accomplish an agency function in accordance with the Privacy Act of 1974, Public Law 93-579, December 31, 1974 (5 USC 552a) and applicable agency regulations. Violation of the Act may involve the imposition of criminal penalties.

The Privacy Act System of Records applicable to this project is Number 09-25-0200. This document is incorporated into this contract as Attachment 12.

ARTICLE H.4. SUBCONTRACTING PROVISIONS

a. Small Business Subcontracting Plan

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

b. Subcontracting Reports

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

(1) Individual Subcontract Reports (ISR)

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

April 30th
October 30th

(2) Summary Subcontract Report (SSR)

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

October 30th

For both the Individual and Summary Subcontract Reports, the [Contracting Officer/Contract Specialist/or title of alternate designee] shall be included as a contact for notification purposes at the following e-mail address:

[Contracting Officer/Contract Specialist, OA, NCI]

ARTICLE H.5. INFORMATION SECURITY

The Statement of Work (SOW) requires the contractor to develop or access Federal automated information systems; therefore, the contractor shall comply with the "DHHS Information Security Program Policy" (<http://www.hhs.gov/read/irmpolicy/FINALHHSInformationSecurityProgramP.doc>) as set forth below. The contractor shall include this provision in any subcontract awarded under this contract.

a. Information Type

**** (NOTE: The resultant contract will include the Information Type, however for the purposes of this RFP, the Information Type is specified in SECTION L.2.b. Technical Proposal Instructions of this RFP.) ****

[] Administrative, Management and Support Information:

[] Mission Based Information:

b. Security Categories and Levels

**** (NOTE: The resultant contract will include the Security Categories and Levels, however for the purposes of this RFP, the Security Categories and Levels are specified in SECTION L.2.b. Technical Proposal Instructions of this RFP.) ****

Confidentiality	Level:	<input type="checkbox"/> Low	<input type="checkbox"/> Moderate	<input type="checkbox"/> High
Integrity	Level:	<input type="checkbox"/> Low	<input type="checkbox"/> Moderate	<input type="checkbox"/> High
Availability	Level:	<input type="checkbox"/> Low	<input type="checkbox"/> Moderate	<input type="checkbox"/> High
Overall	Level:	<input type="checkbox"/> Low	<input type="checkbox"/> Moderate	<input type="checkbox"/> High

c. Position Sensitivity Designations

- (1) The following position sensitivity designations and associated clearance and investigation requirements apply under this contract:

**** **(NOTE: The resultant contract will include the Position Sensitivity Designations, however for the purposes of this RFP, the Position Sensitivity Designations applicable to this RFP are specified in SECTION L.2.b. Technical Proposal Instructions of this RFP.) ******

[] **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 and responsibility, of all IT staff working under the contract. The roster shall be submitted to the Project Officer, with a copy to the Contracting Officer, within 14 days of the effective date of the contract. Any revisions to the Roster as a result of staffing changes shall be submitted within fifteen (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 Investigation 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 employees who have had a background investigation conducted by the U.S. Office of Personnel Management (OPM) within the last five years may only require an updated or upgraded investigation.

- (3) Contractor employees shall comply with the DHHS criteria for the assigned position sensitivity designations prior to performing any work under this contract. The following exceptions apply:

Levels 5 and 1: Contractor 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 preappointment investigation. If the waiver is granted, the Project Officer will provide written authorization for the contractor employee to work under the contract.

d. Systems Security Plan

The contractor shall protect Federal automated information systems that are developed or accessed by the contractor. System security shall be accomplished in accordance with the contractor's System Security Plan dated _____. The plan must:

- (1) Include a detailed plan of present and proposed systems security programs commensurate with the size and complexity of the requirements of the Statement of Work. The contractor shall use the **NIH Systems Security Plan Template** (detailed) at <http://irm.cit.nih.gov/security/secplantemp.doc> or **NIH Systems Security Plan Outline** (outline only) at http://irm.cit.nih.gov/nihsecurity/Security_Plan_Outline.doc.

[OR (To be determined during negotiations)]

- (1) Include a plan of present and proposed systems security programs commensurate with the size and complexity of the requirements of the Statement of Work. The minimum areas to be addressed include, but are not limited to administrative, technical, and physical security as follows:
- (i) Security Awareness Training
 - (ii) Logical Access Control
 - Network (ex: firewall)
 - System (ex: network OS, tcp wrappers, SSH)
 - Application (ex: S-LDAP, SSL)
 - Remote Access (ex: VPN)
 - Monitoring and support (ex: IDS, pager, NOC)
 - (iii) Protection against data loss
 - OS security (ex: patch management, configuration)
 - Application security (ex: patch management)
 - Database security
 - Back-up and recovery
 - Fault tolerance, high availability
 - (iv) Malicious Code Protection (ex: Antivirus, filtering of e-mail attachments, etc)
 - (v) Physical Security
 - Access control (ex: locks, guards)
 - Power conditioning and/or UPS
 - Air conditioning
 - Fire protection

Include an acknowledgment of its understanding of the security requirements.

Provide similar information for any proposed subcontractor developing or accessing an AIS.

e. Rules of Behavior

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

f. Information Security Training

Each contractor employee shall complete the NIH Computer Security Awareness Training (<http://irtsectraining.nih.gov/>) prior to performing any contract work, and on an annual basis thereafter, during the period of performance of this contract.

The contractor shall maintain a listing by name and title of each individual working under this contract that has completed the NIH required training. Any additional security training completed by contractor staff shall be included on this listing.

Contractor staff shall complete the following additional training prior to performing any work under this contract:

**** ***[Additional courses will be listed here in the resultant contract, if applicable.]*** ****

g. Personnel Security Responsibilities

The contractor shall perform and document the actions identified in the "Employee Separation Checklist", attached and made a part of this contract, when a contractor employee terminates work under this

contract. All documentation shall be made available to the Project Officer and/or Contracting Officer upon request

h. Commitment to Protect Departmental Information Systems and Data

(1) Contractor Agreement

The Contractor shall not release, publish, or disclose sensitive Department 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 sensitive 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 employee who may have access to sensitive Department information under this contract shall complete 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.

i. References

1. DHHS Information Security Program Policy: <http://www.hhs.gov/ohr/manual/pssh.pdf>
2. DHHS Personnel Security/Suitability Handbook: <http://www.hhs.gov/ohr/manual/pssh.pdf>
3. NIST Special Publication 800-16, Information Technology Security Training Requirements: <http://csrc.nist.gov/publications/nistpubs/800-16/800-16.pdf>
Appendix A-D: <http://csrc.nist.gov/publications/nistpubs/800-16/AppendixA-D.pdf>
4. NIST SP 800-18, Guide for Developing Security Plans for Information Technology Systems: <http://csrc.nist.gov/publications/nistpubs/index.html>
5. NIST SP 800-60, Guide for Mapping Types of Information and Information Systems to Security Categories, Volume I: <http://csrc.nist.gov/publications/nistpubs/800-60/SP800-60V1-final.pdf>
6. NIST SP 800-60, Guide for Mapping Types of Information and Information Systems to Security Categories, Volume II: <http://csrc.nist.gov/publications/nistpubs/800-60/SP800-60V2-final.pdf>
7. NIST SP 800-64, Security Considerations in the Information System Development Life Cycle: <http://csrc.nist.gov/publications/nistpubs/800-64/NIST-SP800-64.pdf>
8. NIH Computer Security Awareness Training Course: <http://irtsectraining.nih.gov/>
9. Roster of Employees Requiring Suitability Investigations: <http://ais.nci.nih.gov/forms/Suitability-roster.xls>
10. NCI Information Technology Security Policies, Background Investigation Process: <http://ais.nci.nih.gov/>
11. NIH Systems Security Plan Template (detailed): <http://irm.cit.nih.gov/security/secplantemp.doc>
12. NIH Systems Security Plan Outline (outline only): http://irm.cit.nih.gov/nihsecurity/Security_Plan_Outline.doc
13. NIH Information Technology General Rules of Behavior: <http://irm.cit.nih.gov/security/nihitrob.html>
14. Commitment To Protect Non-Public Information - Contractor Agreement: <http://irm.cit.nih.gov/security/Nondisclosure.pdf>

ARTICLE H.6. ELECTRONIC AND INFORMATION TECHNOLOGY STANDARDS

Pursuant to Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d) as amended by P.L.105-220 under Title IV (Rehabilitation Act Amendments of 1998) all Electronic and Information Technology (EIT) developed, procured, maintained and/or used under this contract shall be in compliance with the "Electronic and Information Technology Accessibility Standards" set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the "Access Board") in 36 CFR Part 1194. The complete text of Section 508 Final Standards can be accessed at <http://www.access-board.gov/>.

The standards applicable to this requirement are listed below:

- 1194.21 - Software applications and operating systems
- 1194.22 - Web-based intranet and internet information and applications

ARTICLE H.7. 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.8. CONFIDENTIALITY OF INFORMATION

The following information is covered by HHSAR 352.224-70, Confidentiality of Information (MARCH 2005):

The contractor shall ensure the confidentiality of the following data or information which may be made available to the resultant contractor in the course of the work to be performed hereunder:

1. All information regarding clinical trials protocols;
2. Proprietary information contained in Investigational New Drug Applications (INDs) and reports to the Food and Drug Administration containing such data;
3. Confidential Information in all Adverse Drug Reaction (ADR) documentation;
4. Proprietary data in NCI databases;
5. Any protocol related proprietary data.

Data (source documents, datafiles, databases) and computer software will be collected, maintained and/or developed under the resultant contract. Data is to be used, maintained and disposed of by the Contractor only as approved by the Project Officer and Contracting Officer. Upon completion of the contract, all databases shall be delivered to NCI.

ARTICLE H.9. PUBLICATION AND PUBLICITY

The contractor shall acknowledge the support of the National Institutes of Health whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

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

ARTICLE H.10. PRESS RELEASES

- a. Pursuant to Public Law(s) cited in paragraph b., below, 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.

b.	Public Law and Section No.	Fiscal Year	Period Covered
----	-----------------------------------	--------------------	-----------------------

[Applicable information to be included at award]

ARTICLE H.11. 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** 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.12. 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)

- 2. Noncommercial Supply Items Warranty

YEAR 2000 WARRANTY--NONCOMMERCIAL SUPPLY ITEMS

The contractor warrants that each noncommercial item of hardware, software, and firmware delivered or developed under this contract and listed below 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, when used in accordance with the item documentation provided by the contractor, provided that all listed or unlisted items (e.g., hardware, software and firmware) used in combination with such listed item properly exchange date data with it. If the contract requires that specific listed items must perform as a system in accordance with the foregoing warranty, then that warranty shall apply to those listed items as a system. The duration of this warranty and the remedies available to the Government for breach of this warranty shall be as defined in, and subject to, the terms and limitations of any general warranty provisions of this contract provided that notwithstanding any provision to the contrary in such warranty provision(s), or in the absence of any such warranty provision(s), the remedies available to the Government under this warranty shall include repair or replacement of any listed item whose noncompliance is discovered and made known to the contractor in writing within ninety (90) days after acceptance. Nothing in this warranty shall be construed to limit any rights or remedies the Government may otherwise have under this contract with respect to defects other than Year 2000 performance.

YEAR 2000 COMPLIANT ITEMS

(End of Clause)

- 3. Commercial Supply Products Warranty

YEAR 2000 WARRANTY--COMMERCIAL SUPPLY ITEMS

The contractor warrants that each hardware, software and firmware product delivered under this contract and listed below 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, when used in accordance with the product documentation provided by the contractor, provided that all listed or unlisted products (e.g., hardware, software, firmware) used in combination with such listed product properly exchange date data with it. If the contract requires that specific listed products must perform as a system in accordance with the foregoing warranty, then that warranty shall apply to those listed products as a system. The duration of this warranty and the remedies available to the Government for breach of this warranty shall be as defined in, and subject to, the terms and limitations of the contractor's standard commercial warranty or warranties contained in this contract, provided that notwithstanding any provision to the contrary in such commercial warranty or warranties, the remedies available to the Government under this warranty shall include repair or replacement of any listed product whose non-compliance is discovered and made known to the contractor in writing within ninety (90) days after acceptance. Nothing in this warranty shall be construed to limit any rights or remedies the Government may otherwise have under this contract with respect to defects other than Year 2000 performance.

YEAR 2000 COMPLIANT ITEMS

(End of Clause)

ARTICLE H.13. ANTI -LOBBYING

- a. Pursuant to Public Law(s) cited in paragraph c., below, contract funds shall only be used for normal and recognized executive-legislative relationships. Contract funds shall not be used, for publicity or propaganda purposes; or for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support or defeat legislation pending before the Congress or any State legislature, except in presentation to the Congress or any State legislature itself.
- b. Contract funds shall not be used to pay salary or expenses of the contractor or any agent acting for the contractor, related to any activity designed to influence legislation or appropriations pending before the Congress or any State legislature.

c.	Public Law and Section	Fiscal Year	Period Covered
No.			

[Applicable information to be included at award]

ARTICLE H.14. OBTAINING AND DISSEMINATING BIOMEDICAL RESEARCH RESOURCES

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

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

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:

General Clauses for a Cost-Reimbursement Service Contract

The complete listing of these clauses may be accessed at:

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

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 clause(s) will be made part of the resultant contract:

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 **52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns** (July 2005).

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

[] Offeror elects to waive the evaluation preference."

- (2) FAR Clause **52.219-25, Small Disadvantaged Business Participation Program--Disadvantaged Status and Reporting** (October 1999).
- (3) FAR Clause **52.224-1, Privacy Act Notification** (April 1984).
- (4) FAR Clause **52.224-2, Privacy Act** (April 1984).
- (5) FAR Clause **52.227-14, Rights in Data - General** (June 1987).
- (6) FAR Clause **52.230-2, Cost Accounting Standards** (April 1998).

- (7) FAR Clause **52.237-3, Continuity of Services** (January 1991).
- (8) FAR Clause **52.239-1, Privacy or Security Safeguards** (August 1996).
- (9) FAR Clause **52.242-3, Penalties for Unallowable Costs** (May 2001).
- (10) FAR Clause **52.247-63, Preference for U.S. Flag Air Carriers** (June2003).
- (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** (April 1984 - including revisions mandated by the 1/3/2005 Federal Register notice which was effective March 2005).

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) (OMB Bulletin 81-16).

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

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

This contract incorporates the following clauses in full text.

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

- a. 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 20210, 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.

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	See Attachment Section at the end of this RFP
Attachment 2:	Proposal Intent Response Sheet	http://rcb.cancer.gov/rcb-internet/forms/intent.jsp
Attachment 3:	Statement of Work	Linked to the Attachment Title

TECHNICAL PROPOSAL ATTACHMENTS: (The following attachments must be completed, where applicable, and submitted with the Technical Proposal.)

Attachment No.	Title	Location
Attachment 4:	Summary of Related Activities	http://www.niaid.nih.gov/contract/forms.htm

BUSINESS PROPOSAL ATTACHMENTS: (The following attachments must be completed, where applicable, and submitted with the Business Proposal.)

Attachment No.	Title	Location
Attachment 5:	Proposal Summary and Data Record, NIH-2043	http://www.niaid.nih.gov/contract/forms.htm
Attachment 6:	Small Business Subcontracting Plan	http://rcb.cancer.gov/rcb-internet/forms/sb-subplan-nci.pdf
Attachment 7:	Breakdown of Proposed Estimated Costs (plus Fee) with Excel Spreadsheet	http://oamp.od.nih.gov/contracts/BUSCOST.HTM http://oamp.od.nih.gov/Division/DFAS/spshexcls
Attachment 8:	Offeror's Points of Contact	http://www.niaid.nih.gov/contract/forms.htm
Attachment 9:	Certificate of Current Cost or Pricing Data	http://rcb.cancer.gov/rcb-internet/forms/cert-current-cost.pdf
Attachment 10:	Disclosure of Lobbying Activities, OMB Form SF-LLL	http://rcb.cancer.gov/rcb-internet/forms/sfllin.pdf

INFORMATIONAL ATTACHMENTS: (The following Attachments and Reports will become part of any contract resulting from this RFP and will be required during contract performance.)

Attachment No.	Title	Location
Attachment 11:	Invoice/Financing Request and Contract Financial Reporting Instructions--Cost Reimbursement, NIH(RC)-4	http://rcb.cancer.gov/rcb-internet/forms/rc4.pdf
Attachment 12:	Privacy Act System of Records <i>System of Records No. 09-25-0200 is applicable to this RFP.</i>	http://oma.od.nih.gov/ms/privacy/pa-files/read02systems.htm
Attachment 13:	Procurement of Certain Equipment, NIH(RC)-7	http://www.niaid.nih.gov/contract/forms/NIH-RC-7.pdf
Attachment 14:	Disclosure of Lobbying Activities, OMB Form SF-LLL	http://rcb.cancer.gov/rcb-internet/forms/sfillin.pdf
Attachment 15:	Commitment To Protect Non-Public Information Contractor Agreement	http://irm.cit.nih.gov/security/Nondisclosure.pdf
Attachment 16:	Roster of Employees Requiring Suitability Investigations	http://ais.nci.nih.gov/forms/Suitability-roster.xls
Attachment 17:	Employee Separation Checklist	http://rcb.cancer.gov/rcb-internet/forms/Emp-sep-checklist.pdf

PART IV - REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

SECTION K 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.

IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST COMPLETE SECTION K AND SUBMIT IT AS PART OF YOUR BUSINESS PROPOSAL.

SECTION L - INSTRUCTIONS, CONDITIONS AND NOTICES TO OFFERORS

1. GENERAL INFORMATION

a. INSTRUCTIONS TO OFFERORS--COMPETITIVE ACQUISITION [FAR Provision 52.215-1 (January 2004)]

(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 legend, specifying the particular portions of the proposal which are to be restricted in accordance with the conditions of the legend. The Government's determination to withhold or disclose a record will be based upon the particular circumstances involving the record in question and whether the record may be exempted from disclosure under the Freedom of Information Act. The legend reads:

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 should 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 legends or statements differing in substance from the above legend may not be considered for award. The Government reserves the right to reject any proposal submitted with a nonconforming legend.

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

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

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

(4) The Government intends to evaluate proposals and award a contract without discussions with offerors (except clarifications as described in FAR 15.306(a)). Therefore, the offeror's initial proposal should contain the offeror's best terms from a cost or price and technical standpoint. The Government reserves the right to conduct discussions if the Contracting Officer later determines them to be necessary. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals.

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

(End of Provision)

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

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

b. NAICS CODE AND SIZE STANDARD

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

- (1) The North American Industry Classification System (NAICS) code for this acquisition is 541690.
- (2) The small business size standard is \$6,500,000.

THIS REQUIREMENT IS NOT SET-ASIDE FOR SMALL BUSINESS. However, the Federal Acquisition Regulation (FAR) requires in EVERY solicitation, (except for foreign acquisitions) the inclusion of the North American Industry Classification (NAICS) Code and corresponding size standard which best describes the nature of the requirement in the solicitation.

c. TYPE OF CONTRACT AND NUMBER OF AWARDS

It is anticipated that one award will be made from this solicitation and that the award will be made on about October 30, 2006.

It is anticipated that the award from this solicitation will be a multiple-year cost reimbursement completion type contract with a period of performance of 7 years, and that incremental funding will be used [see Section L.2.c. Business Proposal Instructions].

d. 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 total 7 year effort to be approximately 324,688 labor hours. This information is furnished for the offeror's information only and is not to be considered restrictive for proposal purposes.

e. 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.

f. 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.

g. 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.

h. COMPARATIVE IMPORTANCE OF PROPOSALS

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

i. **REFERENCE MATERIALS**

The Statement of Work (Attachment 3 of this Request for Proposals) contains links to websites that may be used as reference materials for proposal preparation. The resources are located on the final page of the Statement of Work and are also noted as exhibits within the body of the Statement of Work where applicable. Failure of offerors to examine the reference materials prior to proposal preparation and submission will be at the offeror's risk.

j. **PREPARATION COSTS**

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

k. **SERVICE OF PROTEST (AUGUST 1996) - FAR 52.233-2**

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

Theresa H. Shroff
Contracting Officer
Office of Acquisitions
National Cancer Institute
EPS, Room 6008
6120 EXECUTIVE BLVD MSC 7195
BETHESDA MD 20892-7195

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

(End of Provision)

l. **AVAILABILITY OF THE "FEDERAL ADP AND TELECOMMUNICATIONS STANDARDS INDEX."**

Copies of the "Federal ADP and Telecommunications Standards Index" can be purchased from the U.S. Government Printing Office, Superintendent of Documents, Washington, DC 20402.

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 addresses, 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 must include direct cost and resources information, such as labor-hours and categories and applicable rates, materials, subcontracts, travel, etc., and associated costs so that the offeror's understanding of the project may be evaluated (See Attachment entitled, TECHNICAL PROPOSAL COST SUMMARY). However, the technical proposal should **not** include pricing data relating to individual salary information, indirect cost rates or

amounts, fee amounts (if any), and total costs. The technical proposal should disclose your technical approach in as much detail as possible, including, but not limited to, the requirements of the technical proposal instructions.

(5) **Alternate Proposals**

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

(6) **Evaluation of Proposals**

The Government will evaluate 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 procurement, 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) **Standards for Privacy of Individually Identifiable Health Information**

The Department of Health and Human Services (DHHS) issued final modifications to the "Standards for Privacy of Individually Identifiable Health Information," the "Privacy Rule," on August 14, 2002. The Privacy Rule is a federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information and is administered and enforced by the DHHS Office for Civil Rights (OCR). Those who must comply with the Privacy Rule (classified under the Rule as "covered entities" must do so by April 14, 2003 (with the exception of small health plans which have an extra year to comply).

Decisions about the applicability and implementation of the Privacy Rule reside with the contractor and his/her institution. The OCR Web site (<http://www.hhs.gov/ocr/>) provides information of the Privacy Rule, including a complete Regulation Text and a set of decision tools on "Am I a covered entity?" Information on the impact of the HIPAA Privacy Rule on NIH processes involving the review, award, and administration

of grants, cooperative agreements and contracts can be found at: <http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html>.

(10) Specific Copyright Provisions Applicable to Software Development and/or Enhancement(s)

Under the provisions of the Rights in Data General clause (52.227-14), contractors must seek permission to establish a copyright for software and associated data generated under a contract. As a general rule, permission is normally granted provided, a paid-up, world-wide, irrevocable, nonexclusive license to the government is provided. This is to advise offerors that for this project, the government intends to assert additional copyright permissions under this contract. [The scope of the Government's interest in the copyright will be determined during negotiations.]

(11) 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 General Accounting 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.

(12) Selection of Offerors

- a) The acceptability of the [scientific and] technical portion of each [research] contract proposal will be evaluated by a technical review committee. The committee will evaluate each proposal in strict conformity with the evaluation criteria of the RFP, utilizing point scores and written critiques. The committee may suggest that the Contracting Officer request clarifying information from an offeror.
- b) The business portion of each contract proposal will be subjected to a cost and price analysis, management analysis, etc.
- c) If award will be made without conducting discussions, offerors may be given the opportunity to clarify

certain aspects of their proposal (e.g., the relevance of an offeror's past performance information and adverse past performance information to which the offeror has not previously had an opportunity to respond) or to resolve minor or clerical errors.

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

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

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

While it is 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. This process will take into consideration the results of the technical evaluation, the past performance evaluation (if applicable) and the cost analysis.
- 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.

(13) Institutional Responsibility Regarding Conflicting Interests of Investigators

EACH INSTITUTION MUST:

- (a) Maintain an appropriate written, enforced policy on conflict of interest that complies with 42 CFR Part 50 Subpart F and/or 45 CFR Part 94 as appropriate and inform each investigator of the Institution's policy, the Investigator's reporting responsibilities, and the applicable regulations. If the Institution carries out the NIH funded research through subgrantees, contractors or collaborators, the Institution must take reasonable steps to ensure that Investigators working for such entities comply with the regulations, either by requiring those investigators to comply with the Institution's policy or by requiring the entities to provide assurances to the Institution that will enable the Institution to comply with the regulations.
- (b) Designate an Institutional official(s) to solicit and review financial disclosure statements from each Investigator who is planning to participate in NIH-funded research.
- (c) Require that by the time an application/proposal is submitted to the NIH each investigator who is planning to participate in the NIH-funded research has submitted to the designated official(s) a listing

- of his/her known Significant Financial Interests (and those of his/her spouse and dependent children): (i) that would reasonably appear to be affected by the research for which the NIH funding is sought; and (ii) in entities whose financial interests would reasonably appear to be affected by the research. All financial disclosures must be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.
- (d) Provide guidelines consistent with the regulations for the designated official(s) to identify conflicting interests and take such actions as necessary to ensure that such conflicting interests will be managed, reduced, or eliminated.
 - (e) Maintain records, identifiable to each award, of all financial disclosures and all actions taken by the institution with respect to each conflicting interest for: (1) in the case of grants, at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 CFR Part 74.53(b) and (2) in the case of contracts, 3 years after final payment or, where applicable, for the other time period specified in 48 CFR Part 4 Subpart 4.7, Contract Records Retention.
 - (f) Establish adequate enforcement mechanisms and provide for sanctions where appropriate.
 - (g) Certify, in each application/proposal for funding to which the regulations applies, that:
 - 1) there is in effect at the Institution a written and enforced administrative process to identify and manage, reduce or eliminate conflicting interests with respect to all research projects for which funding is sought from the NIH;
 - 2) prior to the Institution's expenditure of any funds under the award, the Institution will report to the awarding component the existence of a conflicting interest (but not the nature of the interest or other details) found by the Institution and assure that the interest has been managed, reduced or eliminated in accord with the regulations; and for any interest that the Institution identifies as conflicting subsequent to the expenditure of funds after award, the report will be made and the conflicting interest managed, reduced, or eliminated, at least on a temporary basis within sixty days of that identification;
 - 3) the Institution agrees to make information available, upon request, to the awarding component regarding all conflicting interests identified by the Institution and how those interested have been managed, reduced, or eliminated to protect the research from bias; and
 - 4) the Institution will otherwise comply with the regulations.

Institutional Management of Conflicting Interests

- (a) The designated official(s) must: (1) review all financial disclosures; and (2) determine whether conflict of interest exists, and if so, determine what actions should be taken by the Institution to manage, reduce or eliminate such conflict of interest. **A conflict of interest exists when the designated official(s) reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the NIH-funded research.**

Examples of conditions or restrictions that might be imposed to manage actual or potential conflicts of interests include, but are not limited to:

- (i) public disclosure of significant financial interests;
 - (ii) monitoring of research by independent reviewers;
 - (iii) modification of the research plan;
 - (iv) disqualification of the Investigator(s) from participation in all or a portion of the research funded by the awarding component;
 - (v) divestiture of significant financial interests; or
 - (vi) severance of relationships that create actual or potential conflicts of interests.
- (b) An Institution may require the management of other conflicting financial interests in addition to those

described in paragraph (a) of this section, as the Institution deems appropriate.

(14) Past Performance Information

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

A list of the last five contracts completed during the past three years and all contracts currently in process 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 that are newly formed entities without prior contracts should list contracts and subcontracts as required above for all key personnel.

Include the following information for each contract or subcontract:

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. Standard Industrial Code

The offeror shall submit comparable information on all subcontractors that the offeror proposes to perform a major subcontract under this effort. For the purpose of this solicitation, a "major subcontract" is defined as a subcontract that is greater than \$500,000.

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

- b) Each offeror will be evaluated on its performance under existing and prior contracts for similar products or services. 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.

(15) Electronic and Information Technology Accessibility

Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by P.L.105-220 under Title IV (Rehabilitation Act Amendments of 1998) and the Architectural and Transportation Barriers Compliance Board Electronic and Information Technology (EIT) Accessibility Standards (36 CFR part 1194) require that all EIT acquired must ensure that:

- a. Federal employees with disabilities have access to and use of information and data that is comparable to the access and use by Federal employees who are not individuals with disabilities; and
- b. Members of the public with disabilities seeking information or services from an agency have access to and use of information and data that is comparable to the access to and use of information and data by members of the public who are not individuals with disabilities.

This requirement includes the development, maintenance, and/or use of EIT products/services, therefore, any proposal submitted in response to this solicitation must demonstrate compliance with the established EIT Accessibility Standards.

Further information about Section 508 is available via the Internet at <http://www.section508.gov> .

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

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

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

- a) Data Universal Numbering System (DUNS) Number, FAR Clause 52.204-6 (October 2003).
- b) Facilities Capital Cost of Money, FAR Clause 52.215-16, (October 1997).
- c) Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8, (October 1997).
- d) Preaward On-Site Equal Opportunity Compliance Evaluation, (Over \$10,000,000), FAR Clause 52.222-24, (February 1999).

b. TECHNICAL PROPOSAL INSTRUCTIONS

TECHNICAL PROPOSAL INSTRUCTIONS

General

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 will be organized, staffed, and managed. Information should be provided which will demonstrate your understanding and management of important events or tasks.

Background

Current Model for Monitoring DCP Trials

Currently, DCP sponsored Phase I and Phase II cancer prevention trials may be conducted under grants, cooperative agreements, or one of two contracting mechanisms. The two contracting mechanisms are the Master Agreement Holder (MAH) mechanism (awarded 1993) and the Consortia mechanism (awarded 2002).

Under the MAH mechanism, multiple master agreement contracts were awarded, each with a five year period of performance. Master Agreement funding takes place solely through the award of a protocol contract. Typically, the contracts were carried out solely by the Master agreement Holder though, in some cases, other collaborating organizations participated.

In 2002, six institutions were awarded contracts under the DCP consortia mechanism. These institutions have established infrastructures that will support the clinical trials work throughout the contracted time frame. Each of the six institutions conducts DCP sponsored Phase I and Phase II cancer prevention research in multiple organ sites and has DCP-approved participating organizations to assist in conducting these prevention research trials.

The current model of data collection and study management of DCP cancer prevention clinical trials varies based on contracting mechanism. Some institutions use study-specific paper Case Report Forms to manually collect clinical data while other institutions use electronic Case Report Forms via the Oracle® Clinical-Remote Data Capture system. These data are entered into either a local, clinical research management organization (CRMO), or other database, depending on the DCP-approved study arrangements. These data are reported to DCP in the form of progress reports. The format of these progress reports is specified by DCP; progress reports are required to be submitted on a quarterly basis for contracts and semiannually or annually for grants and cooperative agreements. At the completion of each study, the Institution PIs are required to submit to DCP either a final report with detailed study results and analysis, or a final study manuscript. Templates containing the required data elements for case report forms, progress reports, final reports and other data collection tools can be found at <http://www3.cancer.gov/prevention/CTR/>

Currently, study progress reports, final reports, and study manuscripts are reviewed by the DCP Medical and/or Scientific Monitors and are forwarded to the DCP Regulatory Support Contractor for quality assurance review and database abstraction. The information supplied in the reports is used to complete the annual FDA report for DCP-sponsored IND studies. In the role of either the financial or IND sponsor, DCP must effectively monitor the conduct of clinical trials. Currently, to fulfill this obligation, the DCP Monitoring Contractor must physically visit the sites to both monitor study progress and to audit submitted data against the source document. The use of the DCP databases will facilitate concurrent monitoring of study progress by DCP personnel.

DCP Informatics

The current cancer prevention clinical trials database (OC-RDC) was developed to collect and manage cancer prevention clinical trials data from the DCP Prevention Consortia lead organizations and/or participating organizations using a remote data capture. The OC-RDC database has been configured to exchange data with

DESK. The offeror should use standards for interoperability and compatibility adopted by NCI (National Cancer Institute) Center for Bioinformatics (NCICB). These standards include the use of controlled vocabularies available in the Enterprise Vocabulary System (EVS - <http://ncicb.nci.nih.gov/core/EVS>), Common Data Elements (CDEs) in the Cancer Data Standards Repository (caDSR - <http://ncicb.nci.nih.gov/core/caDSR>) and other infrastructure requirements. Any database created to manage prevention clinical trial data shall be compliant with NCI informatics standards, relevant industry standards, and applicable Health Insurance Portability Protection Act (HIPAA) standards for data integrity, confidentiality and security.

The offeror should demonstrate their ability to maintain compliance with all regulatory requirements concerning participant records in electronic format that are created, modified, maintained, archived, retrieved, or transmitted under agency record requirements and also applies to any electronic record submitted to the agency. The offeror should demonstrate their ability to develop and implement a system that will support compliance with relevant participant consent provisions of HIPAA.

As appropriate, the offerors proposal should demonstrate an understanding of the requirement to comply with appropriate Federal Requirements for computer systems (including hardware and software). The offerors proposal should demonstrate an understanding of the requirement to comply with 21 CFR Part 11 for computer systems (including hardware and software) to ensure that the integrity of data in the database is maintained.

The offeror should demonstrate an understanding of the appropriate change management activities to implement effective configuration management to maintain the integrity of work products. The Cancer Biomedical Informatics Grid (caBIG™) and NCI's Center for Bioinformatics (NCICB) have identified requirements for documenting changes in system configuration. An offeror will be expected to be cognizant of these guidelines and expected to document all versions/releases of all systems documentation (user and technical) as well as source code for open source systems and system components in the caBIG™ CVS (Code Versioning System) repository.

The offerors proposal should demonstrate their ability to evaluate system integration opportunities in order to eliminate system redundancy and to increase functionality and productivity. In this regard, the Contractor may be required to attend appropriate caBIG™ and DCP informatics meetings. DCP may consult with the leadership of the National Cancer Institute Center for Bioinformatics (NCICB) regarding any new informatics purchases or conversions.

(1) **Technical Discussions**

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

1. Technical Approach

a) Statement of Work

i. 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 which is relevant to this project and your proposed approach. This should support the scope of the project as you perceive it.

ii. Approach

- Use as many subparagraphs, appropriately titled, as needed to clearly outline the general plan of work. Discuss phasing of projects and possible or probable outcome of approaches proposed.

iii. 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.

iv. 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 project. Schedules shall be shown in terms of calendar months from the date of authorization to proceed or, where applicable, from the date of a stated event, as for example, receipt of a required approval by the Contracting Officer. Unless the request for proposal indicates that the stipulated schedules are mandatory, they shall be treated

as desired or recommended schedules. In this event, proposals based upon the Offeror's best alternative schedule, involving no overtime, extra shift or other premium, will be accepted for consideration.

b) TASK 1: Data Management for Participant Cancer Prevention Clinical Trial Data

- The Offeror shall document expertise in developing and maintaining a system for collecting and managing participant level data.
- The Offeror shall propose a plan to meet the defined needs of the DCP based on their past experience in developing similar systems in medical research settings.
- The Offeror shall demonstrate expertise in coordinating data collection and management among multiple entities.

c) TASK 2: Monitoring and Quality Control Auditing of DCP Cancer Prevention Clinical Trials

- The Offeror's proposal shall describe optimal methods for scheduling, staffing and conducting quality control auditing and monitoring visits.
- The Offeror shall provide a plan for ensuring the competency of Clinical Research Associate (CRA)/Clinical Research Coordinator (CRC) staff and consistency of quality control auditing and monitoring visits across sites and among auditors.
- The Offeror shall provide examples of monitoring plans developed in other medical research setting and shall demonstrate knowledge of the unique differences inherent in cancer prevention trials. The description shall include a plan for flagging unexpected adverse events and data inconsistencies. A plan for data validation, error reporting, and data reporting and data correction shall be identified.
- The Offeror shall provide sample SOPs for conducting site visits and samples of site visit reports.

d) TASK 3: Education and Training Support for Staff Conducting DCP Cancer Prevention Clinical Trials

- The Offeror shall describe mechanisms for assessing educational needs of site staff.
- The Offeror shall describe mechanisms for ensuring that site staff is adequately prepared to conduct cancer prevention trials in compliance with ICH Good Clinical Practice guidelines, federal regulatory requirements and all applicable policies as well as NCI DCP policies and guidelines.
- The Offeror shall provide measures for evaluating the success of educational programs for preparing site staff to conduct prevention clinical trials.
- The Offeror should recommend innovate approaches to educate staff that would accommodate persons participating at geographically diverse locations.
- The Offeror shall provide examples of training materials and web-based resources for clinical trials.

e) TASK 4: Support the Development, Maintenance and Integration of Data Transfer and Reporting Mechanisms for Data Collected from Cancer Prevention Clinical Trials

- The Offeror shall document expertise in developing, implementing and maintaining system(s) for data transfer between distinct databases using Oracle ® tools, and in developing and generating data reports.
- The Offeror shall demonstrate the ability to work collaboratively as part of a multi-organizational technical team to support DESK and OC-RDC maintenance and enhancements.

2. Contractor Personnel

- Offerors should assure that personnel proposed for this project shall not be committed on Federal Grant and Contract for more than a total of 100% of their time. If a 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.
- The technical proposal must demonstrate the Offeror's availability and accessibility to DCP staff for on-site meetings held at the DCP offices in Rockville, MD as well as telephone and email contact from DCP Project Officers and staff.
- The Offeror shall provide specific, concise and relevant experience of the persons to fill the position of Project Manager and all other personnel. Curricula vitae for all personnel must be submitted (limit 4 single-sided pages per person).

- For each person listed, the Offeror should indicate the proposed position, the percent of time committed to this project, along with the percentage of time obligated or commitments to other projects (name of project, source of funding, duration). If individuals will have responsibilities in multiples Task Areas, the Offeror should estimate and indicate the percentage of time committed to each Task Area.
- For each person listed, a brief summary must be given of relevant education, training, and experience in system development and management or clinical trials monitoring, indicating employer and dates of employment.
- The Offeror shall provide a cross-tabulation of personnel with respect to capabilities and experience relevant to capability requirements specified in the RFP.
- The Offeror shall discuss methods for assuming responsibility for activities currently being provided by the incumbent Contractor as well as methods for the transfer of responsibilities to a potential successor at the end of the proposed contract.
- For each task discussed in the Statement of Work, the Offeror shall show the composition of the task group, its general qualifications, and recent experience with similar equipment or programs. Special mention shall be made of direct technical supervisors and key technical personnel, and the approximate percentage of the total time each will be available for this program.
- The Offeror shall demonstrate that Contractor employees shall be available on short notice, and under conditions of multiple and competing tasks.
- Within the total level of effort, Offerors should indicate the specific level of effort that they consider appropriate for each function outlined in the Statement of Work.
- The Offeror shall provide a personnel chart that indicates the hierarchical line of supervisory authority, and indicates which Contractor employee(s) shall perform the various tasks. When appropriate, include a hierarchical line of supervision authority with subcontractor employees.
- For all proposed personnel who are not currently members of the Offeror's staff, a letter of commitment or other evidence of availability is required. A resume does not meet this requirement. Commitment letters for use of consultants and other personnel to be hired must include:
 - The specific items or expertise they will provide.
 - Their availability to the project and the amount of time anticipated.
 - Willingness to act as a consultant

NOTE: Although there are no minimum educational requirements for any contractor personnel on this contract, the Offeror shall disclose the educational preparation and area(s) of expertise for all key personnel proposed. Each person will be evaluated on his or her own merit. There are no geographic restrictions regarding the official, physical business location of the Offeror.

3. Organizational Experience/Support Capabilities

- Offerors should describe in detail prior experience of the organization in furnishing services similar to each area described in the Statement of Work. The proposal should include sufficient information to demonstrate the previous effectiveness of the Offeror in similar or related work. Include documentation with specific reference to applicable contract numbers, date of agreements and dollar volume. This documentation should include a clear and concise description of this project(s) and should indicate the project sponsor (e.g. pharmaceutical company, Government contract or grant, etc.) for each of the described projects. References, including phone numbers, should be provided.
- The relationship of the proposed working group within the organizational structure of the Offeror

should be described as well as how this relationship might facilitate performance of this project. Information should be provided on how staff training needs will be met (including replacement staff) and how the organization would support the Project Manager in resolving problems or special situations. Describe the management plan for the selection of subcontractors and consultants. Please describe the hierarchical line of supervisory authority.

- Include a statement of the priority your organization would place on this work effort as compared to other commitments now or reasonably expected during the proposed period of performance of the contract.

4. Facilities and Equipment

The Offerors shall provide detailed information regarding the facilities available for use on this project, or shall clearly describe how they will be available at the start of the project. The Offerors will demonstrate experience with state-of-the-art information technology (biomedical literature searching, retrieving, and abstracting, sources of information for relevant searching, internet communication and security management, document imaging, data base management, presentation graphics and electronic conferencing)

Some storage requirements shall be conducted in other than DCP facilities and the Contractor shall be required to provide suitable space and equipment to permit their staff to perform off- Government site file maintenance and storage. The site shall have easy access to copy and fax machines, telephones with voice messaging, computers, document scanning, and laser printers to help facilitate report preparation and record keeping functions. The Contractor site will adhere to all fire codes including a dry-fire suppression system. Offerors should submit a floor plan showing the site space that would be dedicated to this project. Offeror should indicate equipment, e.g., computers, processors, and software available for this project. In addition, the Offeror should describe procedures for quality control of data entry, system validation, and security.

There must be adequacy of facilities for storage space for required files and other resource material. Information from the contractor site must be readily available to DCP staff as needed, within twenty-four hours of the request. Information should be transferred rapidly via electronic means whenever possible. The Contractor will preferably have a work location that will ensure timely responses to requests for information or staff. The Contractor should have equipment for manual and computerized literature searches, skill in web site design and maintenance, ability to post documents and databases to the web site, and additional equipment and knowledge of word processing, desktop printing, document scanning, laser printing, fax, audiovisual equipment, presentation graphics, and teleconferencing and e-conferencing. Secure facilities, as previously described, must be available for storage and protection of hard copy data, magnetic/optical storage, media, and archival material.

In the event that a new contractor is selected during recompetition, the contractor shall be responsible for the transfer of all information and other material to the new contractor site. The contractor should propose a transition period of not more than one month. The contractor, if not the incumbent, shall propose a detailed plan to move the current operation to the contractor facility. This plan shall include a plan to start up the operation at the new facility and become operational within one month of contract award. Provisions for the transfer of all electronic data to the DCP informatics system must be addressed.

(2) Technical Evaluation

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

(3) Additional Technical Proposal Information

- a) Proposals which merely offer to conduct a program in accordance with the requirements of the Government's scope of work will not be eligible for award. The Offeror must submit an explanation of the proposed technical approach in conjunction with the tasks to be performed in achieving the project objectives.
- b) The technical evaluation is conducted in accordance with the weighted technical evaluation criteria by an initial review panel. This evaluation produces a numerical score (points) which is based upon the information contained in the Offeror's proposal only.

(4) **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.

5) **Obtaining and Disseminating Biomedical Research Resources**

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

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

This policy, entitled, "Sharing Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts," (Federal Register Notice, December 23, 1999 [64 FR 72090]) will be included in any contract awarded from this solicitation. It can be found at the following website: <http://ott.od.nih.gov/NewPages/64FR72090.pdf>.

(a) **Sharing Research Data**

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

[If the resultant contract is part of a collaborative program involving multiple sites, the data sharing will be governed by a dissemination plan to be developed jointly following award. Offerors must include in their proposals a statement of willingness to work collaboratively after award with the other funded sites to prepare a joint dissemination plan. Coordinating Center proposals should describe methods to coordinate the dissemination planning and implementation. The Coordinating Center must include a budget and justification for any additional costs of this collaborative effort.]

(6) **Information Technology Systems Security**

IMPORTANT NOTE TO OFFERORS: The following information shall be addressed in a separate section of the Technical Proposal entitled, "Information Security."

The Statement of Work (SOW) requires the successful offeror to develop or access Federal automated information systems. Pursuant to the DHHS Information Security Program Policy (<http://www.hhs.gov/read/irmpolicy/FINALHHSInformationSecurityProgramP.doc>), the following requirements apply:

(a) Information Type

Administrative, Management and Support Information:

Mission Based Information:

(b) Security Categories and Levels

Confidentiality	Level:	<input type="checkbox"/> Low	<input checked="" type="checkbox"/> Moderate	<input type="checkbox"/> High
Integrity	Level:	<input type="checkbox"/> Low	<input checked="" type="checkbox"/> Moderate	<input type="checkbox"/> High
Availability	Level:	<input checked="" type="checkbox"/> Low	<input type="checkbox"/> Moderate	<input type="checkbox"/> High

Overall Level: Low Moderate High

(c) Position Sensitivity Designations

Prior to award, the Government will determine the position sensitivity designation for each contractor employee that the successful offeror proposes to 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 IT staff working under the contract. The Government will determine the appropriate level of suitability

investigation required for each staff member.

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

(d) Systems Security Plan

The offeror's proposal must:

- (1) Include a detailed plan of its present and proposed systems security programs commensurate with the size and complexity of the requirements of the Statement of Work. Offerors must use:

NIH Systems Security Plan Template (detailed) at:

<http://irm.cit.nih.gov/security/secplantemp.doc>; or

NIH Systems Security Plan Outline (outline only) at:

http://irm.cit.nih.gov/nihsecurity/Security_Plan_Outline.doc.

(e) Information Systems Security Training

DHHS policy requires contractors 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 employee has completed the NIH Computer Security Awareness Training course (<http://irtsectraining.nih.gov/>) prior to performing any contract work, and on an annual basis thereafter, 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.

(f) References

- (1) DHHS Information Security Program Policy: <http://www.hhs.gov/read/irmpolicy/FINALHHSInformationSecurityProgramP.doc>
- (2) DHHS Personnel Security/Suitability Handbook: <http://www.hhs.gov/ohr/manual/pssh.pdf>
- (3) NIH Systems Security Plan Template: <http://irm.cit.nih.gov/security/secplantemp.doc>
- (4) NIH Systems Security Plan Outline: http://irm.cit.nih.gov/nihsecurity/Security_Plan_Outline.doc
- (5) NIH Computer Security Awareness Training Course: <http://irtsectraining.nih.gov/>
- (6) NIST Special Publication 800-16, Information Technology Security Training Requirements: <http://csrc.nist.gov/publications/nistpubs/800-16/800-16.pdf>
Appendix A-D: <http://csrc.nist.gov/publications/nistpubs/800-16/AppendixA-D.pdf>
- (7) NIST SP 800-18, Guide for Developing Security Plans for Information Technology Systems: <http://csrc.nist.gov/publications/nistpubs/index.html>
- (8) NIST SP 800-60, Guide for Mapping Types of Information and Information Systems to Security Categories, Volume I:

<http://csrc.nist.gov/publications/nistpubs/800-60/SP800-60V1-final.pdf>

- (9) NIST SP 800-60, Guide for Mapping Types of Information and Information Systems to Security Categories, Volume II:

<http://csrc.nist.gov/publications/nistpubs/800-60/SP800-60V2-final.pdf>

- (10) NIST SP 800-64, Security Considerations in the Information System Development Life Cycle:

<http://csrc.nist.gov/publications/nistpubs/800-64/NIST-SP800-64.pdf>

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;
- (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 \$10,000,000 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. 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.
5. 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) **Small Business Subcontracting Plan**

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

- a) THIS PROVISION DOES NOT APPLY TO SMALL BUSINESS CONCERNS.
- b) The term "subcontract" means any agreement (other than one involving an employer-employee relationship) entered into by a Federal Government prime contractor or subcontractor calling for supplies or services required for the performance of the original contract or subcontract. This includes, but is not limited to, agreements/purchase orders for supplies and services such as equipment purchase, copying services, and travel services.
- c) The offeror understands that:
- (1) No contract will be awarded unless and until an acceptable plan is negotiated with the Contracting Officer which plan will be incorporated into the contract, as a material part thereof.
- (2) An acceptable plan must, in the determination of the Contracting Officer, provide the maximum practicable opportunity for Small Businesses, Small Disadvantaged

Businesses, Women-Owned Small businesses, HubZone Small Businesses, Veteran-Owned Small Businesses, and Service Disabled Veteran-Owned Small Businesses to participate in the performance of the contract.

- (3) If a subcontracting plan acceptable to the Contracting Officer is not negotiated within the time limits prescribed by the contracting activity and such failure arises out of causes within the control and with the fault or negligence of the offeror, the offeror shall be ineligible for an award. The Contracting Officer shall notify the Contractor in writing of the reasons for determining a subcontracting plan unacceptable early enough in the negotiation process to allow the Contractor to modify the plan within the time limits prescribed.
 - (4) Prior compliance of the offeror with other such subcontracting plans under previous contracts will be considered by the Contracting Officer in determining the responsibility of the offeror for award of the contract.
 - (5) It is the offeror's responsibility to develop a satisfactory subcontracting plan with respect to Small Business Concerns, Small Disadvantaged Business Concerns, Women-Owned Small Business Concerns, HubZone Small Business Concerns, Veteran-Owned Small Business Concerns, and Service Disabled Veteran-Owned Small Business Concerns that each such aspect of the offeror's plan will be judged independent of the other.
 - (6) The offeror will submit, as required by the Contracting Officer, subcontracting reports in accordance with the instructions thereon, and as further directed by the Contracting Officer. Subcontractors will also submit these reports to the Government's Contracting Officer or as otherwise directed, with a copy to the prime Contractor's designated small and disadvantaged business liaison.
- d) Each plan must contain the following:
- (1) Goals, expressed in terms of percentages of total planned subcontracting dollars, for the use of Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Business Concerns as subcontractors.
 - (2) A statement of total dollars planned to be subcontracted. A statement of total dollars to be subcontracted to each of the following type of small business concerns: Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.
 - (3) A description of the principal types of supplies and services to be subcontracted with an identification of which supplies and services are expected to be subcontracted to Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and/or Service Disabled Veteran-Owned Small Business Concerns.
 - (4) A description of the method used to develop the subcontracting goals.
 - (5) A description of the method used to identify potential sources for solicitation purposes.
 - (6) A statement as to whether or not indirect costs were included in establishing subcontracting goals. If they were, a description of the method used to determine the proportionate share of indirect costs to be incurred with Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.
 - (7) The name of the individual employed by the offeror who will administer the

offeror's subcontracting program and a description of his/her duties.

- (8) A description of the efforts the offeror will make to assure that Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses have an equitable chance to compete for subcontracts.
- (9) Assurances that the offeror will include in all subcontracts the contract clause "Utilization of Small Business Concerns." Assure that all subcontractors, other than small businesses, in excess of \$500,000 adopt a plan similar to the plan agreed upon by the offeror.
- (10) Assurances that the offeror (and any required subcontractors) will cooperate in studies or surveys as required and submit required reports (SF 294 and SF 295) to the Government.
- (11) List the types of records the offeror will maintain to demonstrate procedures that have been adopted to comply with the requirement and goals in the plan, including establishing source lists. Also, the offeror shall describe its efforts to locate Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses and award subcontracts to them.

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

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

23% for Small Business; _5_% for Small Disadvantaged Business; _5_% for Women-Owned Small Business; _3_% for HUBZone Small Business; and _3_% for Veteran-Owned Small Business and Service-Disabled Veteran-Owned Small Business.

(4) **HUBZone Small Business Concerns**

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

(5) **Extent of Small Disadvantaged Business Participation**

In accordance with FAR Subpart 15.304(c)(4), the extent of participation of Small Disadvantaged Business (SDB) concerns in performance of the contract in the authorized NAICS Subsectors shall be evaluated in unrestricted competitive acquisitions expected to exceed \$500,000 (\$1,000,000 for construction) subject to certain limitations (see FAR 19.1202-1 and 19.1202-2(b)). The dollar amounts cited above include any option years/option quantities that may be included in this solicitation. The definition of a "small disadvantaged business" is cited in FAR 19.001.

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

The Department of Commerce determines, on an annual basis, by Subsectors, as contained in the North American Industry Classification System (NAICS) code, and region, if any, the

authorized SDB procurement mechanisms and applicable factors (percentages). The NAICS codes can be found at:

<http://www.sba.gov/size>

The Department of Commerce website for the annual determination for NAICS codes* is:

<http://www.arnet.gov/References/sdbadjustments.htm>.

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

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

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

EXAMPLE

Targets for SDB Participation - NAICS Subsector 223

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

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

(6) **Total Compensation Plan - Instructions**

- a) 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 part of their business proposal, will submit a "Total Compensation Plan" (salaries and fringe benefits) for these professional employees for evaluation purposes.
- b) 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).
- c) Evaluation for award, therefore, will include an assessment of the Total Compensation Plan submitted by each offeror.

(7) **Total Compensation Plan - Evaluation**

a) **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.

b) **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.

c) **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.

d) **Federal Acquisition Regulation Clauses incorporated by Reference**

FAR Clause 52.222-46, Evaluation of Compensation for Professional Employees

(FEBRUARY 1993).

(8) **Qualifications of the Offeror**

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

a) **General Experience**

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

b) **Organizational Experience Related to the RFP**

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

c) **Performance History**

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

d) **Pertinent Contracts**

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

e) **Pertinent Grants**

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

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

(9) **Other Administrative Data**

a) **Property**

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

- (a) An explanation that the item is for a special use essential to the direct performance of the contract and the item will be used exclusively for the purpose. Office equipment such as desks, office machines, etc., will not be provided under a contract except under very exceptional circumstances.
- (b) No practical or economical alternative exists (e.g., rental, capital investment) that can be used to perform the work.
- (2) The offeror shall identify Government-owned property in its possession and/or Contractor titled property acquired from Federal funds, which it proposes to use in the performance of the prospective contract.
- (3) The management and control of any Government property shall be in accordance with DHHS Publication (OS) 686 entitled, "Contractor's Guide for Control of Government Property (1990)," a copy of which will be provided upon request.

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

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

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

c) **Financial Capacity**

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

d) **Incremental Funding**

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

HHSAR 352.232-75, Incremental Funding (January 2001)

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

(End of provision)

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

- The prospective Contractor has specifically identified or proposed facilities capital cost of money in its cost proposal and elects to claim this cost as an allowable cost under the contract. Submit Form CASB-CMF (see FAR 31.205-10).
- The prospective Contractor has not specifically identified or proposed facilities capital cost of money in its proposal and elects not to claim it as an allowable cost under the contract.

(10) **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>

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

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

(12) **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>

(13) **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

a. GENERAL

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

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

b. 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.

FACTORS

Proposals submitted in response to this RFP will be evaluated in accordance with the following factors listed in descending order of importance. Documentation should be provided to validate experience, capabilities, and skill level wherever appropriate.

Technical Approach

Weight = 40%

1.1 The offeror's approach to the Statement of Work must demonstrate significant knowledge in the fields of clinical trials monitoring support, data management informatics support, and staff education training.

In addition, the following components will be evaluated:

1.2 Proficiency in designing, developing and maintaining a web-based system for electronically submitted clinical trials data using Oracle ® applications.

1.3 Methodology for and level of expertise in scientific informatics management, including database support, producing web-based resources and overall information management of delivery of services.

1.4 Methodology for and level of expertise in coordination and interaction with the DCP staff to accomplish tasks.

1.5 Approach to scientific quality control procedures.

1.6 Transition Plan.

1.7 Plan for use of consultants and/or subcontractors.

Personnel

Weight = 35%

2.1 Relevant managerial experience of appropriately qualified project managers and task leaders in organizing and coordinating the efforts of personnel, including consultants and subcontractors, required to perform the functions described in the Statement of Work

- 2.2 Expertise in assessing customer problems, proposing and implementing identified solutions, maintaining effective communication and problem solving skills, and effective management of resources.
- 2.3 Experience of appropriately qualified personnel in providing data management, database design and development for projects of comparable size and complexity within a medical research environment.
- 2.4 Experience in serving as task/project leaders for applications using Oracle® applications.
- 2.5 Knowledge of DHHS Code of Federal Regulations, Good Clinical Practice guidelines, FDA requirements for study sponsors, NIH and NCI requirements for the conduct of clinical trials including ethical and regulatory requirements.
- 2.6 Availability, qualifications, experience, education, and competence of professional, technical, and other personnel, to include proposed subcontractors and consultants as evidenced by resumes, endorsements, and explanations of previous efforts.
- 2.7 Soundness of the proposed staff time or labor hours, appropriateness of personnel classifications (professional, technical, others), necessity for type and quantity of Contractor staff, material and facilities proposed.
- 2.8 Validity of proposed consulting/subcontracting and suitability of consulting/subcontracting staff expertise for this project.

Experience and Resources of Company

Weight = 20%

- 3.1 Organizational experience in monitoring and auditing biomedical clinical trials in multiple settings.
- 3.2 Organizational experience in managing receipt, review, and reporting of clinical trials data.
- 3.3 Organizational experience in design, development, and maintenance of web-based databases using Oracle® applications.
- 3.4 Organizational experience and oversight of relevant clinical trials conducted at single sites, multiple sites, and with pharmaceutical collaborators.
- 3.5 Availability of additional, appropriately qualified staff to support heavier workloads and/or to provide backup for members of the project team.

Facilities

Weight = 5%

- 4.1 A Disaster Recovery Plan
- 4.2 Availability of resources (equipment, facilities, and personnel) to accomplish the tasks in the Statement of Work, within the stated timeframes.

c. PAST PERFORMANCE FACTOR

An evaluation of offerors' past performance information will be conducted prior to any communications with offerors leading to establishment of the competitive range. However, this evaluation will not be conducted on any offeror whose proposal will not be admitted to the competitive range on the basis of the results of the evaluation of factors other than past performance.

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

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

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

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

d. **EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION**

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

The extent of the offeror's Small Disadvantaged Business Participation Targets will be evaluated before determination of the competitive range. Evaluation of SDB participation will be assessed based on consideration of the information presented in the offeror's proposal. The Government is seeking to determine whether the offeror has demonstrated a commitment to use SDB concerns for the work that it intends to perform.

Offers will be evaluated on the following sub-factors:

- (a) Extent to which SDB concerns are specifically identified
- (b) Extent of commitment to use SDB concerns
- (c) Complexity and variety of the work SDB concerns are to perform
- (d) Realism of the proposal
- (e) Past performance of offerors in complying with subcontracting plan goals for SDB concerns and monetary targets for SDB participation
- (f) Extent of participation of SDB concerns in terms of the value of the total acquisition.

SOLICITATION ATTACHMENTS INCLUDED WITH THE RFP

The following pages include Attachment(s) applicable to this RFP as specified in SECTION J
- List of Attachments

PACKAGING AND DELIVERY OF THE PROPOSAL

Your proposal shall be organized as specified in Section L.2., "Instructions to Offerors" - General Instructions. Shipment and marking shall be as indicated below.

EXTERNAL PACKAGE MARKING

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

**"RFP NO. N02-CN-65002-46
TO BE OPENED BY AUTHORIZED GOVERNMENT PERSONNEL ONLY"**

PLEASE READ THE FOLLOWING INFORMATION CAREFULLY:

****PLEASE NOTE - THE TECHNICAL AND BUSINESS PROPOSAL SHALL BE SENT IN SPLIT SHIPMENTS TO TWO LOCATIONS. ****

NUMBER OF COPIES

TECHNICAL AND BUSINESS PROPOSAL: ORIGINAL* AND 2 COPIES TO:

If hand-delivered or delivery service

Elizabeth B. Dean
Contract Specialist
Office of Acquisitions
National Cancer Institute
Executive Plaza South, Room 6010
6120 Executive Boulevard
Rockville, Maryland 20852

If using U.S. Postal Service

Elizabeth B. Dean
Contract Specialist
Office of Acquisitions
National Cancer Institute
Executive Plaza South, Room 6010
6120 EXECUTIVE BLVD MSC 7195
BETHESDA MD 20892-7195

TECHNICAL AND BUSINESS PROPOSAL: TEN COPIES TO:

If hand-delivered or delivery service

Maggie House, RN, BSN, OCN
Nurse Consultant
Prostate and Urologic Cancer Research Group
Division of Cancer Prevention
National Cancer Institute, NIH, DHHS
Executive Plaza North, Room 2104
6130 Executive Boulevard
Rockville, Maryland 20852

If using U.S. Postal Service

Maggie House, RN, BSN, OCN
Nurse Consultant
Prostate and Urologic Cancer Research Group
Division of Cancer Prevention
National Cancer Institute, NIH, DHHS
Executive Plaza North, Room 2104
6130 EXECUTIVE BLVD MSC 7318
BETHESDA MD 20892-7318

*THE ORIGINALS MUST BE READILY ACCESSIBLE FOR DATE STAMPING PURPOSES.

NOTE: The U.S. Postal Service's "Express Mail" does not deliver to the Rockville, Maryland address. Any package sent to the Rockville address via this service will be held at a local post office for pick-up. The Government is not responsible for picking up any mail at a local post office. If a proposal is not received at the place, date, and time specified herein, it will be considered a "late proposal."