

SOLICITATION

SECTION A - SOLICITATION/CONTRACT FORM

1. Requisition or other Purchase Authority: _____		
2. Request for Proposal (RFP) Number: N02CM67000-11	3. Issue Date: February 22, 2016	4. Set Aside: <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes See Part IV Section L
5. Title : Preclinical Pharmacokinetic and Pharmacology Evaluations of Agents Being Developed for Cancer Patients		
6. ISSUED BY: Office of Acquisitions National Cancer Institute National Institutes of Health Riverside Five 8490 Progress Drive, Suite 400 Frederick, MD 21701-4998	7. SUBMIT OFFERS TO: See Part III, Section J, "Packaging and Delivery of the Proposal," ATTACHMENT 1 of this Solicitation.	
<p>8. The deadline for receipt of questions submitted electronically, in writing, to the Contracting Officer (CO) shall be March 7, 2016 at 2:00 PM EST. Refer to Section L.1. for completed instructions. Proposals for furnishing the supplies and/or services in THE SCHEDULE will be received at the place specified in, and in the number of copies specified in Attachment 1, "Packaging and Delivery of the Proposal," until 2:00 PM EST local time on March 22, 2016. 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."</p>		
<p>9. This solicitation requires delivery of proposals as stated in ATTACHMENT 1, "PACKAGING AND DELIVERY OF THE PROPOSAL." If proposals are required to be delivered to two different locations, the OFFICIAL POINT OF RECEIPT for determining TIMELY DELIVERY is the address provided for the OFFICE OF ACQUISITIONS.</p> <p>IF YOUR PROPOSAL IS NOT RECEIVED BY THE CONTRACTING OFFICER OR HIS DESIGNEE AT THE PLACE AND TIME SPECIFIED FOR THE OFFICE OF ACQUISITIONS, THEN IT WILL BE CONSIDERED LATE AND HANDLED IN ACCORDANCE WITH subparagraph (c)(3) of FAR Clause 52.215-1, Instructions to Offerors--Competitive Acquisition," LOCATED IN SECTION L.1. OF THIS SOLICITATION.</p>		
<p>10. Offeror must be registered in the Central Contractor Registry (CCR) prior to award of a contract. Offerors must access the CCR through The System for Award Management (SAM) at http://www.sam.gov</p>		
<p>11. FOR INFORMATION CALL: Alexis D. Hudak, Contracting Officer PHONE: (301) 624-8753 e-MAIL: alexis.hudak@nih.gov COLLECT CALLS WILL NOT BE ACCEPTED.</p>		
		Alexis D. Hudak Contracting Officer Office of Acquisitions Room 4037

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PART I - THE SCHEDULE

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

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

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

The purpose of this acquisition is to obtain analytical, pharmacokinetic, metabolism, pharmacodynamic, and other pharmacologic data on new agents (including small molecules, peptides, oligonucleotides, and other biologicals) for the treatment of cancer. Awardees will implement and validate appropriate established analytical methods to quantify compounds in biological fluids and tissues from multiple species and rapid pharmacokinetic assessments to the NCI. Data generated will be used in all phases of the drug development process, from lead selection and development to the support of early clinical trials. For those agents that are selected for clinical trial, the reports generated under these contracts will comprise a portion of the IND submission to the FDA.

ARTICLE B.2. PRICES/COSTS

- a. This is a Multiple Award Indefinite Quantity contract as contemplated by FAR 16.504. The Contractor shall be reimbursed by the Government in an amount not less than a total of \$5,000 (minimum) nor more than a total of \$9,900,000 (maximum) for successful performance of this contract.
- b. The costs set forth in this ARTICLE will cover the contract period July 1, 2016 through June 30, 2021.
- c. The Government will compete and award Task Orders based on the work described in SECTION C of this contract.
- d. Ordering procedures are described in The TASK ORDER PROCEDURE Article in SECTION G of this contract.

ARTICLE B.3. PROVISIONS APPLICABLE TO DIRECT COSTS

This article will prohibit or restrict the use of contract funds, unless otherwise approved by the Contracting Officer. The following is a list of items that may be included in the resultant contract as applicable. 1) Conferences & Meetings, 2) Food for Meals, Light Refreshments & Beverages, 3) Promotional Items, 4) Acquisition, by purchase or lease, of any interest in real property; 5) Special rearrangement or alteration of facilities; 6) Purchase or lease of any item of general purpose office furniture or office equipment regardless of dollar value; 7) Travel Costs including Foreign Travel; 8) Consultant Costs; 9) Subcontract Costs; 10) Patient Care Costs; 11) Accountable Government Property; 12) Printing costs; and 13) 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 December 20, 2015, attached hereto and made a part of this Solicitation (See SECTION J - List of Attachments).

ARTICLE C.2. REPORTING REQUIREMENTS

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

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

All paper/hardcopy documents/reports submitted under this contract shall be printed or copied, double-sided, on at least 30 percent post consumer fiber paper, whenever practicable, in accordance with FAR 4.302(b).

a. Technical Progress Reports

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

For proposal preparation purposes only, it is estimated that in addition to the required electronic versions one (1) hard copy of the Final Report will be required:

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

b. Other Reports/Deliverables

1. Biological Samples

If stated in individual Task Order list of deliverables, the Contractor shall package and ship specified animal fluids and tissues to NCI-designated laboratories. All applicable USDOT regulations for packaging and shipment of hazardous materials shall be followed.

2. Section 508 Annual Report

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

3. Report of USDA-Designated Biobased Products

In accordance with FAR clause 52.223-2, Affirmative Procurement of Biobased Products Under Service and Construction Contracts, the contractor shall report to <http://www.sam.gov>, with a copy to the Contracting Officer any USDA-designated biobased products purchased during the period of October 1-September 30 of each contract year. This report shall be submitted no later than October 31 of each year during contract performance and on the expiration date of the contract.

4. Data Updates

Pharmacokinetic (e.g., C vs. t values, PK parameters) and other numerical data shall be submitted to the Contracting Officer Representative (COR) on a real-time basis (weekly, unless there are no data to report) in a standard spreadsheet format (e.g., Excel). Additional specifications may be included in the Task Order list of deliverables.

5. Invention Report

Due annually on the anniversary date of the task order.

ARTICLE C.3. INVENTION REPORTING REQUIREMENT

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

The annual utilization report shall be submitted in accordance with the DELIVERIES Article in SECTION F of this contract. Thereafter, reports shall be due on or before the ___ Calendar day following the reporting period.] The final invention statement (see FAR 27.303(b)(2)(ii)) shall be submitted on the expiration date of the contract. All reports shall be sent to the following address:

Contracting Officer
National Institutes of Health
National Cancer Institute
Office of Acquisition
Treatment and Support Branch (TSB)
8490 Progress Drive, Suite 400
Frederick, Maryland 21701-4998

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

To assist contractors in complying with invention reporting requirements of the clause, the NIH has developed "Interagency Edison," an electronic invention reporting system. Use of Interagency Edison is required as it streamlines the reporting process and greatly reduces paperwork. Access to the system is through a secure interactive Web site to ensure that all information submitted is protected. Interagency Edison and information relating to the capabilities of the system can be obtained from the Web (<https://public.era.nih.gov/iedison/public/nihprocs.jsp>), or by contacting the Extramural Inventions and Technology Resources Branch, OPERA, NIH.

SECTION D - PACKAGING, MARKING AND SHIPPING

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

Please see the Statement of Work (SOW) for shipping and distribution instructions for this contract.

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 Contracting Officer Representative (COR) is the authorized representative of the Contracting Officer.
- c. Inspection and acceptance will be performed at:
National Cancer Institute
Division of Cancer Treatment & Diagnosis
9609 Medical Center Drive
Rockville, MD 20850-7448

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 **52.246-2, Inspection of Supplies - Fixed Price** (August 1996).

FAR Clause **52.246-3, Inspection of Supplies - Cost-Reimbursement** (May 2001).

FAR Clause **52.246-4, Inspection of Services - Fixed Price** (August 1996).

FAR Clause **52.246-5, Inspection of Services - Cost-Reimbursement** (April 1984).

FAR Clause **52.246-16, Responsibility for Supplies** (April 1984).

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

The period of performance of this contract shall be from July 1, 2016 through June 30, 2021.

ARTICLE F.2. DELIVERIES

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

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

Item	Description	Quantity	Delivery Schedule
(1)	Data Updates	One electronic copy	Due weekly, unless no data to report
(2)	Monthly Task Order Progress Report	One electronic copy	Due on or before the 15th calendar day following, the end of the reporting period, if prescribed in Task Order
(3)	Final Task Order Report (and sub-reports if required)	One electronic copy	Due on or before the expiration date of the Task Order or 15th calendar day after technical work is complete, whichever comes first
(4)	Invention Report	One electronic copy	Due annually on/or before the anniversary date of the contract
(5)	Section 508	One electronic copy to the COR and one electronic copy to the CO	Due annually on/or before the anniversary date of the contract

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

Addressee	Deliverable Item No	Quantity
Contracting Officer Representative (COR) Developmental Therapeutics Program (DTP) National Cancer Institute email address TBD	Items (1) through (5)	As required above
Contracting Officer (CO) Office of Acquisitions (OA) National Cancer Institute ncibranchcinvoices@mail.nih.gov	Items (1) through (5)	As required above

ARTICLE F.3. CLAUSES INCORPORATED BY REFERENCE, FAR 52.252-2 (FEBRUARY 1998)

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

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:

52.242-15, Stop Work Order (August 1989)

Alternate I (April 1984) is applicable to this contract (Cost-Reimbursement Task Orders).

Alternate I (April 1984) is not applicable to this contract (Firm Fixed-Price Task Orders).

SECTION G - CONTRACT ADMINISTRATION DATA

ARTICLE G.1. CONTRACTING OFFICER'S REPRESENTATIVE (COR)

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

To be specified prior to award.

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

The Contracting Officer is the only person with authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the statement of work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor for any costs incurred during the performance of this contract; (5) otherwise change any terms and conditions of this contract; or (6) sign written licensing agreements. Any signed agreement shall be incorporated by reference in Section K of the contract.

The Government may unilaterally change its COR designation.

ARTICLE G.2. KEY PERSONNEL, HHSAR 352.237-75 (December 2015)

The key personnel specified in this contract are considered to be essential to work performance. At least 30 days prior to the contractor voluntarily diverting any of the specified individuals to other programs or contracts the Contractor shall notify the Contracting Officer and shall submit a justification for the diversion or replacement and a request to replace the individual. The request must identify the proposed replacement and provide an explanation of how the replacement's skills, experience, and credentials meet or exceed the requirements of the contract (including, when applicable, Human Subjects Testing requirements). If the employee of the contractor is terminated for cause or separates from the contractor voluntarily with less than thirty days notice, the Contractor shall provide the maximum notice practicable under the circumstances. The Contractor shall not divert, replace, or announce any such change to key personnel without the written consent of the Contracting Officer. The contract will be modified to add or delete key personnel as necessary to reflect the agreement of the parties.

(End of Clause)

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

Name	Title
To be determined	

ARTICLE G.3. TASK ORDER PROCEDURE

This contract provides for the issuance of Task Orders on a negotiated basis as follows:

a. **General**

Only the Contracting Officer may issue Task Orders to the Contractor, providing specific authorization or direction to perform work within the scope of the contract and as specified in the Statement of Work. Unless specifically authorized by the Contracting Officer, the Contractor shall not commence work until a fully executed

Task Order has been awarded. The Contractor may incur costs under this contract in performance of task orders and task order modifications issued in accordance with this ARTICLE.

No other costs are authorized unless otherwise specified in the contract or expressly authorized by the Contracting Officer.

b. Requesting Task Order Proposals.

The Contracting Officer or a designated individual may solicit responses to requirements from Contractors within a technical area covered by a task order requirement in writing. A Task Order Request for Proposals (TORFP) will be prepared and issued for each task order requirement.

Generally, the Task Order Request for Proposal (TORFP) will include but is not limited to the following:

1. Statement of Work;
2. Reporting Requirements and Deliverables;
3. Proposal Due Date and Location to Deliver Proposals;
4. Period of Performance of Task Order;
5. Anticipated type of Task Order;
6. Technical Proposal Instructions;
7. Business proposal Instructions;
8. Evaluation Factors for Award

All contract clauses contained this contract shall be incorporated in the TORFP and the resultant task order. If conflicts exist between the contract clauses and the information outlined in the task order, the contract language takes precedence over the information in the task order.

Contractors are not required to propose on all TORFPs. Those eligible Contractors that decide not to submit a proposal shall advise the Contracting Officer, in writing, of their intention not to submit a proposal on or before the closing date and time established in the TORFP. An election not to propose on a given TORFP will not negatively affect or prohibit a Contractor from competing on future TORFPs. However, it may affect the Contractor's eligibility for continuations or extensions of the resultant Task Order.

c. Competitive Ordering Process.

1. All Contractors within a technical area will receive e-mail notification advising of the availability of each Task Order Request for Proposals (TORFP). All task orders will incorporate all terms of this contract unless otherwise specified in the proposed task order.
2. Contractors will be provided an adequate time to prepare and submit responses based on the Contracting Officer's consideration of the estimated dollar value and complexity of the TORFP. Responses will not be considered a proposal as defined in FAR Part 15. However, the Contractor shall provide information sufficient for consideration in accordance with FAR Part 16. Each TORFP will indicate the criteria to be used for the evaluation of responses. The responses shall demonstrate the Contractors' capability for each criterion to be evaluated. Generally, the Contractor will be asked to demonstrate the following as appropriate:
 - Understanding of the requirements;
 - Experience and capability on similar tasks;
 - Technical approach, methods and procedures for satisfying the requirements with a discussion of potential problems to be encountered and proposed solutions and/or risk mitigation strategies.
 - Procedures for assuring quality of work, products, and deliverables;

- Plan for managing the task order, including meeting requirements and schedules, and performance measures (if applicable);
- Staffing plan with skill levels and level of effort for each individual proposed. Generally, resumes will be required for proposed personnel (if not previously submitted);
- References to evaluate past performance; and
- Cost/Price to perform the task order.

d. Evaluation and Award of Task Order Proposals

The Government will evaluate the Task Order proposals against the requirements of the TORFP. Specifically, the technical evaluation factors, cost/price, past performance and any other factor specifically identified in the TORFP will be used for evaluation of each proposal. In addition, the TORFP will identify the basis for selecting a contractor for award. Generally, technical factors will be significantly more important than cost or price. However, each TORFP will specify how the award decision will be made.

Upon completion of evaluations, the Contracting Officer will issue a task order to the Contractor whose proposal is most advantageous to the government.

The Contracting Officer will notify the Contractor(s) of the selection decision in writing.

e. Fair Opportunity

1. In accordance with FAR 16.505(b)(1)(i), each awardee will be given a fair opportunity to be considered for each order issued over \$3,500 unless the following exception(s) apply:
 - i. The agency need for the supplies or services is so urgent that providing a fair opportunity would result in unacceptable delays.
 - ii. Only one awardee is capable of providing the supplies or services required at the level of quality required because the supplies or services ordered are unique or highly specialized.
 - iii. The order must be issued on a sole-source basis in the interest of economy and efficiency because it is a logical follow-on to an order already issued under the contract, provided that all awardees were given a fair opportunity to be considered for the original order.
 - iv. It is necessary to place an order to satisfy a minimum guarantee.
2. All awardees will be given a fair opportunity to be considered in accordance with the FAR as follows:
 - i. For orders exceeding \$3,500 up to the simplified acquisition threshold, in accordance with FAR 16.505(b)(1)(ii);
 - ii. For orders exceeding the simplified acquisition threshold up to \$5.5 Million, in accordance with 16.505(b)(1)(iii); and,
 - iii. For orders exceeding \$5.5 Million, in accordance with FAR 16.505(b)(1)(iv).

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

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

E-mail: alexis.hudak@nih.gov

The Contractor shall submit an electronic copy of the payment request to the approving official instead of a paper copy. The payment request shall be transmitted as an attachment via e-mail to the address listed above in one of the following formats: MSWord, MS Excel, or Adobe Portable Document Format (PDF). Only one payment request shall be submitted per e-mail and the subject line of the e-mail shall include the Contractor's name, contract number, and unique invoice number. **Note: The original payment request must still be submitted in hard copy and mailed to the designated billing office to meet the requirements of a "proper invoice."**

Central Point of Distribution: ncibranchcinvoices@mail.nih.gov

The Contractor shall submit an electronic copy of the payment request to the Central Point of Distribution mailbox. The payment request shall be transmitted as an attachment via e-mail to the address listed above in one of the following formats: MSWord, MS Excel, or Adobe Portable Document Format (PDF). Only one payment request shall be submitted per e-mail and the subject line of the e-mail shall include the Contractor's name, contract number, and unique invoice number. **Note: The original payment request must still be submitted in hard copy and mailed to the designated billing office to meet the requirements of a "proper invoice."**

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

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

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

- b. One courtesy copy of the original invoice shall be submitted electronically as follows:

1. The Contractor shall scan the original payment request (invoice) in Adobe Portable Document Format (PDF) along with the necessary supporting documentation as one single attachment.
2. **Save** the single attachment (scanned invoice along with any supporting documentation) in the following format: YourVendorName_Invoice number (e.g., if you are submitting Invoice 123456, save the single attachment as "Ash Stevens_Invoice 123456") Note: Please do not use special characters such as (#, \$, %, *, &, !) when saving your attachment. Only the underscore symbol () is permitted.
3. **Transmit** the saved single attachment via e-mail to the appropriate branch's Central Point of Distribution. For the purpose of this contract, the Central Point of Distribution is NCI OA Branch C - ncibranchcinvoices@mail.nih.gov. Only one payment request shall be submitted per e-mail and the subject line of the e-mail shall include the Contract Number_Contract Title_Contractor's Name_unique Invoice number (e.g, HHSN2612XXXXC_Clinical Genetics Support_Ash Stevens_Invoice 12345) **Note: The original payment request must still be submitted in hard copy and mailed to the designated billing office listed in subparagraph a, above, to meet the requirements of a "proper invoice."** Also, The Contractor must certify on the payment request that the electronic courtesy copy is a duplicate of the original invoice mailed to NIH's Office of Financial Management.

2. In addition to the requirements specified in FAR 32.905 for a proper invoice, the Contractor shall include the following information on the face page of all payment requests:
- a. Name of the Office of Acquisitions. The Office of Acquisitions for this contract is National Cancer Institute.
 - b. Federal Taxpayer Identification Number (TIN). If the Contractor does not have a valid TIN, it shall identify the Vendor Identification Number (VIN) on the payment request. The VIN is the number that appears after the Contractor's name on the face page of the contract. *Note: A VIN is assigned to new contracts awarded on or after June 4, 2007, and any existing contract modified to include the VIN number.* If the Contractor has neither a TIN, DUNS, or VIN, contact the Contracting Officer.
 - c. DUNS or DUNS+4 Number. The DUNS number must identify the Contractor's name and address exactly as stated in the contract and as registered in the Central Contractor Registration (CCR) database. If the Contractor does not have a valid DUNS number, it shall identify the Vendor Identification Number (VIN) on the payment request. The VIN is the number that appears after the Contractor's name on the face page of the contract. *Note: A VIN is assigned to new contracts awarded on or after June 4, 2007, and any existing contract modified to include the VIN number.* If the Contractor has neither a TIN, DUNS, or VIN, contact the Contracting Officer.
 - d. Invoice Matching Option. This contract requires a *two-way* match.
 - e. Unique Invoice Number. Each payment request must be identified by a unique invoice number, which can only be used one time regardless of the number of contracts or orders held by an organization.
 - f. The Contract Title: The contract title, is located in block 15B on the first page of the contract document, and shall be placed on all invoices submitted for payment.
 - g. Contract Line Items as follows:

Line Item #	Line Item Description
To be determined	

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

ARTICLE G.5. INVOICE SUBMISSION

- a. Invoice Instructions for NIH Fixed-Price Type Contracts, NIH(RC)-2, are attached and made part of this contract. The Contractor shall follow the attached instructions and submission procedures specified below to meet the requirements of a "proper invoice" pursuant to FAR Subpart 32.9, Prompt Payment.

E-mail: alexis.hudak@nih.gov

The Contractor shall submit an electronic copy of the payment request to the approving official instead of a paper copy. The payment request shall be transmitted as an attachment via e-mail to the address listed above in one of the following formats: MSWord, MS Excel, or Adobe Portable Document Format (PDF). Only one payment request shall be submitted per e-mail and the subject

line of the e-mail shall include the Contractor's name, contract number, and unique invoice number.

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

Central Point of Distribution: ncibranchcinvoices@mail.nih.gov

The Contractor shall submit an electronic copy of the payment request to the Central Point of Distribution mailbox. The payment request shall be transmitted as an attachment via e-mail to the address listed above in one of the following formats: MSWord, MS Excel, or Adobe Portable Document Format (PDF). Only one payment request shall be submitted per e-mail and the subject line of the e-mail shall include the Contractor's name, contract number, and unique invoice number.

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

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

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

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

- b. One courtesy copy of the original invoice shall be submitted electronically as follows:

1. The Contractor shall scan the original payment request (invoice) in Adobe Portable Document Format (PDF) along with the necessary supporting documentation as one single attachment.
2. **Save** the single attachment (scanned invoice along with any supporting documentation) in the following format: YourVendorName_Invoice number (e.g., if you are submitting Invoice 123456, save the single attachment as "Ash Stevens_Invoice 123456") Note: Please do not use special characters such as (#, \$, %, *, &, !) when saving your attachment. Only the underscore symbol (_) is permitted.
3. **Transmit** the saved single attachment via e-mail to the appropriate branch's Central Point of Distribution. For the purpose of this contract, the Central Point of Distribution is NCI OA Branch C - ncibranchcinvoices@mail.nih.gov. Only one payment request shall be submitted per e-mail and the subject line of the e-mail shall include the Contract Number_ Contract Title_ Contractor's Name_ unique Invoice number

(e.g, HHSN2612XXXXXC_Clinical Genetics Support_Ash Stevens_Invoice 12345) **Note: The original payment request must still be submitted in hard copy and mailed to the designated billing office listed in subparagraph a, above, to meet the requirements of a "proper invoice." Also, The Contractor must certify on the payment request that the electronic courtesy copy is a duplicate of the original invoice mailed to NIH's Office of Financial Management.**

2. In addition to the requirements specified in FAR 32.905 for a proper invoice, the Contractor shall include the following information on the face page of all payment requests:

- a. Name of the Office of Acquisitions. The Office of Acquisitions for this contract is National Cancer Institute.

- b. Federal Taxpayer Identification Number (TIN). If the Contractor does not have a valid TIN, it shall identify the Vendor Identification Number (VIN) on the payment request. The VIN is the number that appears after the Contractor's name on the face page of the contract. *Note: A VIN is assigned to new contracts awarded on or after June 4, 2007, and any existing contract modified to include the VIN number.* If the Contractor has neither a TIN, DUNS, or VIN, contact the Contracting Officer.

- c. DUNS or DUNS+4 Number. The DUNS number must identify the Contractor's name and address exactly as stated in the contract and as registered in the Central Contractor Registration (CCR) database. If the Contractor does not have a valid DUNS number, it shall identify the Vendor Identification Number (VIN) on the payment request. The VIN is the number that appears after the Contractor's name on the face page of the contract. *Note: A VIN is assigned to new contracts awarded on or after June 4, 2007, and any existing contract modified to include the VIN number.* If the Contractor has neither a TIN, DUNS, or VIN, contact the Contracting Officer.

- d. Invoice Matching Option. This contract requires a *two-way* match.

- e. Unique Invoice Number. Each payment request must be identified by a unique invoice number, which can only be used one time regardless of the number of contracts or orders held by an organization.

- f. The Contract Title is: Located in block 15B of the first page of the contract document and shall be placed on all invoices submitted for payment.

Preclinical Pharmacokinetic and Pharmacology Evaluations of Agents Being Developed for Cancer Patients.

- g. Contract Line Items as follows:

Line Item #	Line Item Description
To be determined	

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

ARTICLE G.6. PROVIDING ACCELERATED PAYMENT TO SMALL BUSINESS SUBCONTRACTORS, FAR 52.232-40 (December 2013)

- a. Upon receipt of accelerated payments from the Government, the Contractor shall make accelerated payments to its small business subcontractors under this contract, to the maximum extent practicable and prior to when such payment is otherwise required under the applicable contract or subcontract, after receipt of a proper invoice and all other required documentation from the small business subcontractor.

- b. The acceleration of payments under this clause does not provide any new rights under the prompt Payment Act.

- c. Include the substance of this clause, include this paragraph c, in all subcontracts with small business concerns, including subcontracts with small business concerns for the acquisition of commercial items.

(End of Clause)

ARTICLE G.7. INDIRECT COST RATES

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

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

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

ARTICLE G.8. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

a. Contractor Performance Evaluations

Interim and Final evaluations of Contractor performance will be prepared on this contract in accordance with FAR Subpart 42.15. The Final performance evaluation will be prepared at the time of completion of work. In addition to the Final evaluation, Interim evaluation(s) will be prepared Annually (anniversary date of contract award).

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

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

b. Electronic Access to Contractor Performance Evaluations

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

<http://www.cpars.gov>

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. HUMAN MATERIALS

The acquisition and supply of all human specimen material (including fetal material) used under this contract shall be obtained by the Contractor in full compliance with applicable State and Local laws and the provisions of the Uniform Anatomical Gift Act in the United States, and no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

ARTICLE H.3. HUMAN MATERIALS (ASSURANCE OF OHRP COMPLIANCE)

The acquisition and supply of all human specimen material (including fetal material) used under this contract shall be obtained by the Contractor in full compliance with applicable State and Local laws and the provisions of the Uniform Anatomical Gift Act in the United States, and no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

The Contractor shall provide written documentation that all human materials obtained as a result of research involving human subjects conducted under this contract, by collaborating sites, or by subcontractors identified under this contract, were obtained with prior approval by the Office for Human Research Protections (OHRP) of an Assurance to comply with the requirements of 45 CFR 46 to protect human research subjects. This restriction applies to all collaborating sites without OHRP-approved Assurances, whether domestic or foreign, and compliance must be ensured by the Contractor.

Provision by the Contractor to the Contracting Officer of a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263(formerly Optional Form 310), certifying IRB review and approval of the protocol from which the human materials were obtained constitutes the written documentation required. The human subject certification can be met by submission of a self designated form, provided that it contains the information required by the "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263(formerly Optional Form 310).

ARTICLE H.4. NEEDLE DISTRIBUTION

The Contractor shall not use contract funds to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

ARTICLE H.5. ACKNOWLEDGEMENT OF FEDERAL FUNDING

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

ARTICLE H.6. RESTRICTION ON ABORTIONS

The Contractor shall not use contract funds for any abortion.

ARTICLE H.7. DISSEMINATION OF FALSE OR DELIBERATELY MISLEADING INFORMATION

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

ARTICLE H.8. CARE OF LIVE VERTEBRATE ANIMALS, HHSAR 352.270-5(b) (December 2015)

- a. Before undertaking performance of any contract involving animal-related activities where the species is regulated by the United States Department of Agriculture (USDA), the Contractor shall register with the Secretary of Agriculture of the United States in accordance with 7 U.S.C. 2136 and 9 CFR 2.25 through 2.28. The Contractor shall furnish evidence of the registration to the Contracting Officer.
- b. The Contractor shall acquire vertebrate animals used in research from a dealer licensed by the Secretary of Agriculture under 7 U.S.C. 2133 and 9 CFR 2.1 2.11, or from a source that is exempt from licensing under those sections.
- c. The Contractor agrees that the care, use, and intended use of any live vertebrate animals in the performance of this contract shall conform with the Public Health Service (PHS) Policy on Humane Care of Use of Laboratory Animals (PHS Policy), the current Animal Welfare Assurance (Assurance), the Guide for the Care and Use of Laboratory Animals (National Academy Press, Washington, DC) and the pertinent laws and regulations of the United States Department of Agriculture (see 7 U.S.C. 2131 et seq. and 9 CFR subchapter A, Parts 1-4). In case of conflict between standards, the more stringent standard shall govern.
- d. If at any time during performance of this contract, the Contracting Officer determines, in consultation with the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), that the Contractor is not in compliance with any of the requirements and standards stated in paragraphs (a) through (c) above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may, in consultation with OLAW, NIH, terminate this contract in whole or in part, and the Contractor's name may be removed from the list of those contractors with Animal Welfare Assurances.

Note: The Contractor may request registration of its facility and a current listing of licensed dealers from the Regional Office of the Animal and Plant Health Inspection Service (APHIS), USDA, for the region in which its research facility is located. The location of the appropriate APHIS Regional Office, as well as information concerning this program may be obtained by contacting the Animal Care Staff, USDA/APHIS, 4700 River Road, Riverdale, Maryland 20737 (Email: ace@aphis.usda.gov; Web site: (<http://www.aphis.usda.gov/wps/portal/aphis/ourfocus/animalwelfare>).

(End of clause)

ARTICLE H.9. ANIMAL WELFARE

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

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

ARTICLE H.10. INTRODUCTION OF RODENTS AND RODENT PRODUCTS

No rodent or rodent product shall be delivered into the NIH, National Cancer Institute's (contract # TBD) environment (NIH) directly, or through collaborative research or holding facilities under contract to the National Cancer Institute, except by permit. Direct shipments to NIH from a Division of Veterinary Resources (DVR), Office of Research Services (ORS) approved source will be considered exempt. Non-exempt sources must be approved

by permit issued through the DVR, ORS. The permit must be obtained by the Contractor prior to the shipment to NIH of the rodents and/or rodent products. The Contractor must be sure that this permit exists and is current before transferring rodents or rodent products into the NIH, National Cancer Institute's environment. Refusal or negligence to do so will be considered a material breach of contract and may be treated as any other such material breach. Applications for permits should be submitted by facsimile not less than 30 days prior (60 days in situations where quarantine is likely) to shipping date to: NIH Division of Veterinary Resources (DVR), Office of Research Services (ORS), Building 14G, Service Rd. South, Room 102, BETHESDA MD 20892-5210, (301)496-2527, FAX: (301) 402-0352.

ARTICLE H.11. RESTRICTION ON PORNOGRAPHY ON COMPUTER NETWORKS

The Contractor shall not use contract funds to maintain or establish a computer network unless such network blocks the viewing, downloading, and exchanging of pornography.

ARTICLE H.12. GUN CONTROL

The Contractor shall not use contract funds in whole or in part, to advocate or promote gun control.

ARTICLE H.13. CERTIFICATION OF FILING AND PAYMENT OF TAXES

The contractor must be in compliance with Section 518 of the Consolidated Appropriations Act of FY 2014.

ARTICLE H.14. OPTION PROVISION

Unless the Government exercises its option pursuant to the Option Clause set forth in SECTION I., the contract will consist only of the Base Period of the Statement of Work as defined in Sections C and F of the contract. Pursuant to FAR Clause 52.217-6, Option for Increased Quantity set forth in SECTION I. of this contract, the Government may, by unilateral contract modification, require the Contractor to perform additional options set forth in the Statement of Work and also defined in Sections C and F of the contract. If the Government exercises this option, notice must be given at least 60 days prior to the expiration date of this contract, and the [**Use for Cost-Reimbursement Contracts:** estimated cost [plus fixed fee] of the contract will be increased as set forth in the ESTIMATED COST [PLUS FIXED FEE]/ **Use for Fixed-Price Contracts:** price of the contract will be increased as set forth in the OPTION PRICES] Article in SECTION B of this contract.

ARTICLE H.15. SUBCONTRACTING PROVISIONS

a. Small Business Subcontracting Plan

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

b. Subcontracting Reports

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

1. Individual Subcontract Reports (ISR)

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

April 30th
October 30th

Expiration Date of Contract

2. Summary Subcontract Report (SSR)

Regardless of the effective date of this contract, the Summary Subcontract Report shall be submitted annually on the following date for the entire life of this contract:
October 30th

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

TBD
Contracting Officer

ARTICLE H.16. ELECTRONIC AND INFORMATION TECHNOLOGY ACCESSIBILITY, HHSAR 352.239-73(b) (January 2010)

- a. Pursuant to Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998, all electronic and information technology (EIT) products and services developed, acquired, maintained, or used under this contract/order must comply with the "Electronic and Information Technology Accessibility Provisions" set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the "Access Board") in 36 CFR part 1194. Information about Section 508 provisions is available at <http://www.section508.gov/>. The complete text of Section 508 Final provisions can be accessed at <http://www.access-board.gov/guidelines-and-standards>.
 - b. The Section 508 standards applicable to this contract/order are identified in the Statement of Work. The contractor must provide a written Section 508 conformance certification due at the end of each contract/order exceeding \$100,000 when the contract/order duration is one year or less. If it is determined by the Government that EIT products and services provided by the Contractor do not conform to the described accessibility standards in the Product Assessment Template, remediation of the products or services to the level of conformance specified in the Contractor's Product Assessment Template will be the responsibility of the Contractor at its own expense.
 - c. In the event of a modification(s) to this contract/order, which adds new EIT products or services or revises the type of, or specifications for, products or services the Contractor is to provide, including EIT deliverables such as electronic documents and reports, the Contracting Officer may require that the contractor submit a completed HHS Section 508 Product Assessment Template to assist the Government in determining that the EIT products or services support Section 508 accessibility standards. Instructions for documenting accessibility via the HHS Section 508 Product Assessment Template may be found on the HHS Web site (<http://www.hhs.gov/web/508/contracting/technology/vendors.html>).
- [(End of HHSAR 352.239-73(b))]
- d. Prior to the Contracting Officer exercising an option for a subsequent performance period/additional quantity or adding funding for a subsequent performance period under this contract, as applicable, the Contractor must provide a Section 508 Annual Report to the Contracting Officer and Project Officer. Unless otherwise directed by the Contracting Officer in writing, the Contractor shall provide the cited report in accordance with the following schedule. Instructions for completing the report are available in the Section 508 policy on the HHS Office on Disability Web site under the heading Vendor Information and Documents. The Contractor's failure to submit a timely and properly completed report may jeopardize the Contracting Officer's exercising an option or adding funding, as applicable.

Schedule for Contractor Submission of Section 508 Annual Report: Annually

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

ARTICLE H.17. PUBLICATION AND PUBLICITY

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

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

ARTICLE H.18. TASK ORDER/DELIVERY ORDER CONTRACT OMBUDSMAN

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

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

For Non R&D Contracts:
Dr. Richard G. Wyatt
NIH Competition Advocate
1 Center Drive, Room 160, MSC 0151
Bethesda, MD 20892-0151
Phone: (301) 496-4920
E-mail: WyattRG@mail.nih.gov

ARTICLE H.19. 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 website to file a complaint on-line is: <http://oig.hhs.gov/fraud/hotline/> and the mailing address is:

US Department of Health and Human Services
Office of Inspector General
ATTN: OIG HOTLINE OPERATIONS
P.O. Box 23489
Washington, D.C. 20026

a. Transfer of Human Materials

All human materials transferred to the contractor under this contract for the purposes of research shall be accomplished in accordance with the Policy entitled, "Policy for the Transfer of Materials from NIH Intramural Laboratories," located at: <http://www.ott.nih.gov/mta-policy>.

The contractor shall coordinate with the **NCI Technology Transfer Center** (see <http://ttc.nci.nih.gov>) [or the contracting officer will insert name and contact information of the appropriate TDC] to determine the specific terms and conditions for the human materials to be transferred. Generally, the Government and Contractor will enter into Material Transfer Agreement which stipulates the specific terms and conditions relating to the materials being transferred.

ARTICLE H.20. HOTEL AND MOTEL FIRE SAFETY ACT OF 1990 (P.L. 101-391)

Pursuant to Public Law 101-391, no Federal funds may be used to sponsor or fund in whole or in part a meeting, convention, conference or training seminar that is conducted in, or that otherwise uses the rooms, facilities, or services of a place of public accommodation that do not meet the requirements of the fire prevention and control guidelines as described in the Public Law. This restriction applies to public accommodations both foreign and domestic.

Public accommodations that meet the requirements can be accessed at: <http://apps.usfa.fema.gov/hotel/>.

ARTICLE H.21. CONSTITUTION DAY

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

PART II - CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

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

The complete listing of these clauses may be accessed at:
<http://oamp.od.nih.gov/dgs/general-clauses>

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

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

ARTICLE I.1. GENERAL CLAUSES FOR A COST-REIMBURSEMENT SERVICE CONTRACT

ARTICLE I.1. GENERAL CLAUSES FOR A NEGOTIATED FIXED-PRICE SERVICE CONTRACT

ARTICLE I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES

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

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

- a. **Alternate II** (April 1998) of FAR Clause **52.215-2, Audit and Records--Negotiation** (October 2010) is added.
- b. **Alternate IV** (October 2010) of FAR Clause **52.215-21, Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data--Modifications** (October 2010) is added.
- c. FAR Clause **52.215-23, Limitations on Pass-Through Charges** (October 2009), is added.
- d. **Alternate II** (October 2001) of FAR Clause **52.219-9, Small Business Subcontracting Plan** (October 2015) is added.
- e. **Alternate I** (April 1984), of FAR Clause **52.227-1, Authorization and Consent** (December 2007) is deleted in its entirety.
FAR Clause **52.227-11, Patent Rights--Ownership by the Contractor** (May 2014) is deleted in its entirety.
Alternate IV (December 2007), of FAR Clause **52.227-14, Rights In Data--General** (May 2014) is deleted in its entirety.
Alternate II (April 2012), of FAR Clause **52.245-1, Government Property** (April 2012) is deleted in its entirety.
- f. FAR Clause **52.232-17, Interest** (May 2014) is deleted.
- g. 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.]
- h. **Alternate I** (February 2002), of FAR Clause **52.232-25, Prompt Payment** (July 2013) is deleted.
- i. **Alternate I** (April 1984) of FAR Clause **52.243-1, Changes, Fixed Price** (August 1987), is hereby deleted in its entirety and **Alternate II** (April 1984) of FAR Clause **52.243-1, Changes, Fixed Price** (August 1987), is substituted therefor.
- j. FAR Clause **52.216-11, Cost Contract--No Fee** (April 1984) is deleted in its entirety and FAR Clause **52.216-8 Fixed Fee** (June 2011) is substituted therefor.

FAR Clause **52.232-17, Interest** (May 2014) is added.

FAR Clause **52.249-5, Termination for Convenience of the Government (Educational and Other Non-Profit Institutions)** (April 1984) is deleted in its entirety and FAR Clause **52.249-6, Termination (Cost-Reimbursement)** (May 1986) is substituted therefor.

ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES

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

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

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

1. FAR Clause **52.203-13, Contractor Code of Business Ethics and Conduct** (October 2015).
2. FAR Clause **52.203-14, Display of Hotline Poster(s)** (October 2015).

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

Poster(s)	Obtain From"
HHS Contractor Code of Ethics and Business Conduct Poster	http://oig.hhs.gov/fraud/report-fraud/OIG_Hotline_Posters.pdf

3. FAR Clause **52.204-15, Service Contract Reporting Requirements for Indefinite-Delivery Contracts** (January 2014).
4. FAR Clause **52.209-10, Prohibition on Contracting With Inverted Domestic Corporations** (November 2015).
5. FAR Clause **52.210-1, Market Research** (April 2011).
6. FAR Clause **52.217-8, Option to Extend Services** (November 1999).

"..The Contracting Officer may exercise the option by written notice to the Contractor within 7 days.
7. FAR Clause **52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns** (October 2014).

"(c) Waiver of evaluation preference.....
 Offeror elects to waive the evaluation preference."
8. FAR Clause **52.219-28, Post-Award Small Business Program Rerepresentation** (July 2013).
9. FAR Clause **52.222-53, Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services--Requirements** (May 2014).
10. FAR Clause **52.223-2, Affirmative Procurement of Biobased Products Under Service and Construction Contracts** (September 2013).

11. FAR Clause **52.223-3, Hazardous Material Identification and Material Safety Data** (January 1997), with **Alternate I** (July 1995).
 12. FAR Clause **52.227-14, Rights in Data - General** (May 2014).
 13. FAR Clause **52.230-2, Cost Accounting Standards** (October 2015).
 14. FAR Clause **52.230-3, Disclosure and Consistency of Cost Accounting Practices** (October 2015).
 15. FAR Clause **52.230-5, Cost Accounting Standards - Educational Institution** (October 2015).
 16. FAR Clause **52.230-6, Administration of Cost Accounting Standards** (June 2010).
 17. FAR Clause **52.242-3, Penalties for Unallowable Costs** (May 2014).
 18. FAR Clause **52.242-4, Certification of Final Indirect Costs** (January 1997).
 19. FAR Clause **52.243-2, Changes--Cost Reimbursement** (August 1987), **Alternate V** (April 1984).
 20. FAR Clause **52.246-23, Limitation of Liability** (February 1997).
 21. FAR Clause **52.246-25 Limitation of Liability-Services** (February 1997).
 22. FAR Clause **52.248-1, Value Engineering** (October 2010).
 23. FAR Clause **52.251-1, Government Supply Sources** (April 2012).
- b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CHAPTER 3) CLAUSES:
1. HHSAR Clause **352.223-70, Safety and Health** (December 2015).
 2. HHSAR Clause **352.231-70, Salary Rate Limitation** (December 2015).

Note : The Salary Rate Limitation is at the Executive Level II Rate.

See the following website for Executive Schedule rates of pay: <https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/>.

(For current year rates, click on Salaries and Wages/Executive Schedule/Rates of Pay for the Executive Schedule. For prior year rates, click on Salaries and Wages/select Another Year at the top of the page/Executive Schedule/Rates of Pay for the Executive Schedule. Rates are effective January 1 of each calendar year unless otherwise noted.)
 3. HHSAR Clause **352.270-1, Accessibility of Meetings, Conferences and Seminars to Persons with Disabilities** (January 2001).

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

The following clauses are attached and made a part of this contract: No clauses apply.

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.

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

1. FAR Clause 52.209-9, Updates of Publicly Available Information Regarding Responsibility Matters (July 2013)

As prescribed in 9.104-7(c), insert the following clause:

- a. The Contractor shall update the information in the Federal Awardee Performance and Integrity Information System (FAPIS) on a semi-annual basis, throughout the life of the contract, by posting the required information in the System for Award Management (SAM) database at <http://www.acquisition.gov>.
- b. As required by section 3010 of the Supplemental Appropriations Act, 2010 (Pub. L. 111-212), all information posted in FAPIS on or after April 15, 2011, except past performance reviews, will be publicly available. FAPIS consists of two segments--
 1. The non-public segment, into which Government officials and the Contractor post information, which can only be viewed by--
 - i. Government personnel and authorized users performing business on behalf of the Government; or
 - ii. The Contractor, when viewing data on itself; and
 2. The publicly-available segment, to which all data in the non-public segment of FAPIS is automatically transferred after a waiting period of 14 calendar days, except for--
 - i. Past performance reviews required by subpart 42.15;
 - ii. Information that was entered prior to April 15, 2011; or
 - iii. Information that is withdrawn during the 14-calendar-day waiting period by the Government official who posted it in accordance with paragraph (c)(1) of this clause.
- c. The Contractor will receive notification when the Government posts new information to the Contractor's record.
 1. If the Contractor asserts in writing within 7 calendar days, to the Government official who posted the information, that some of the information posted to the non-public segment of FAPIS is covered by a disclosure exemption under the Freedom of Information Act, the Government official who posted the information must within 7 calendar days remove the posting from FAPIS and resolve the issue in accordance with agency Freedom of Information procedures, prior to reposting the releasable information. The contractor must cite 52.209-9 and request removal within 7 calendar days of the posting to FAPIS.
 2. The Contractor will also have an opportunity to post comments regarding information that has been posted by the Government. The comments will be retained as long as the associated information is retained, i.e., for a total period of 6 years. Contractor comments will remain a part of the record unless the Contractor revises them.

3. *As required by section 3010 of Pub. L. 111-212, all information posted in FAPIIS on or after April 15, 2011, except past performance reviews, will be publicly available.*
- d. *Public requests for system information posted prior to April 15, 2011, will be handled under Freedom of Information Act procedures, including, where appropriate, procedures promulgated under E.O. 12600.*

(End of clause)

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

- a. Any supplies and services to be furnished under this contract shall be ordered by issuance of delivery orders or task orders by the individuals or activities designated in the Schedule. Such orders may be issued from 07/01/2016 through 06/30/2021 .
- b. All delivery orders or task orders are subject to the terms and conditions of this contract. In the event of conflict between a delivery order or task order and this contract, the contract shall control.
- c. If mailed, a delivery order or task order is considered "issued" when the Government deposits the order in the mail. Orders may be issued orally, by facsimile, or by electronic commerce methods only if authorized in the Schedule.

(End of clause)

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

- a. **Minimum Order.** When the Government requires supplies or services covered by this contract in an amount of less than _____ [insert dollar figure or quantity], the Government is not obligated to purchase, nor is the Contractor obligated to furnish, those supplies or services under the contract.
- b. **Maximum Order.** The Contractor is not obligated to honor--
 1. Any order for a single item in excess of _____ [insert dollar figure or quantity].
 2. Any order for a combination of items in excess of _____ [insert dollar figure or quantity]; or
 3. A series of orders from the same ordering office within _ days that together call for quantities exceeding the limitation in subparagraph (1) or (2) above.
- c. If this is a requirements contract (i.e., includes the Requirements clause at subsection 52.216-21 of the Federal Acquisition Regulation (FAR)), the Government is not required to order a part of any one requirement from the Contractor if that requirement exceeds the maximum-order limitations in paragraph (b) above.
- d. Notwithstanding paragraphs (b) and (c) above, the Contractor shall honor any order exceeding the maximum order limitations in paragraph (b), unless that order (or orders) is returned to the ordering office within _ days after issuance, with written notice stating the Contractor's intent not to ship the item (or items) called for and the reasons. Upon receiving this notice, the Government may acquire the supplies or services from another source.

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

- a. This is an indefinite-quantity contract for the supplies or services specified, and effective for the period stated, in the Schedule. The quantities of supplies and services specified in the Schedule are estimates only and are not purchased by this contract.

- b. Delivery or performance shall be made only as authorized by orders issued in accordance with the Ordering clause. The Contractor shall furnish to the Government, when and if ordered, the supplies or services specified in the Schedule up to and including the quantity designated in the Schedule as the "maximum." The Government shall order at least the quantity of supplies or services designated in the Schedule as the "minimum."
- c. Except for any limitations on quantities in the Order Limitations clause or in the Schedule, there is no limit on the number of orders that may be issued. The Government may issue orders requiring delivery to multiple destinations or performance at multiple locations.
- d. Any order issued during the effective period of this contract and not completed within that period shall be completed by the Contractor within the time specified in the order. The contract shall govern the Contractor's and Government's rights and obligations with respect to that order to the same extent as if the order were completed during the contract's effective period; provided, that the Contractor shall not be required to make any deliveries under this contract after 6/30/2021 .

(End of clause)

5. FAR Clause 52.217-9, Option to Extend the Term of the Contract (March 2000).

- a. The Government may extend the term of this contract by written notice to the Contractor within the period of performance; provided that the Government gives the Contractor a preliminary written notice of its intent to extend at least 7 days before the contract expires. The preliminary notice does not commit the Government to an extension.
- b. If the Government exercises this option, the extended contract shall be considered to include this option clause.
- c. The total duration of this contract, including the exercise of any options under this clause, shall not exceed 5 years.

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

c. **THERE ARE NO APPLICABLE CLAUSES IN THIS SECTION.**

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

The following documents are incorporated into this RFP:

SOLICITATION ATTACHMENTS

Attachment No.	Title	Location
Attachment 1:	Packaging and Delivery of Proposal (Non R & D)	See attached PDF
Attachment 2:	Proposal Intent Response Sheet	http://ncioa.cancer.gov/oa-internet/forms/intent.jsp
Attachment 3:	Statement of Work	See attached PDF
Attachment 4:	Section K - Representations, Certifications, and Other Statements of Offerors	https://oamp.od.nih.gov/sites/default/files/DGS/FORMS/sectionk_508.pdf

TECHNICAL PROPOSAL ATTACHMENTS

Attachment No.	Title	Location
Attachment 5:	Technical Proposal Cost Summary	See attached PDF
Attachment 6:	Summary of Related Activities	http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/summary-related-activities.pdf
Attachment 7:	Contract Proposal Vertebrate Animal Section (VAS) Worksheet	http://grants.nih.gov/grants/olaw/VAScontracts.pdf
Attachment 8:	HHS Section 508 Product Assessment Template	http://www.hhs.gov/web/508/contracting/technology/vendors.html
Attachment 9:	Additional Technical Proposal Instructions	See attached PDF

BUSINESS PROPOSAL ATTACHMENTS

Attachment No.	Title	Location
Attachment 10:	Proposal Summary and Data Record, NIH-2043	http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/NIH2043.pdf
Attachment 11:	Small Business Subcontracting Plan	See attached PDF
Attachment 12:	Breakdown of Proposed Estimated Costs (plus fee) w/Excel Spreadsheet	http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/buscost.htm
		http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/spshexcl_dec2012.xlsx
Attachment 13:	Offeror's Points of Contact	http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/point-of-contact.pdf
Attachment 14:	Certificate of Current Cost or Pricing Data	http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/cert-current-cost.pdf
Attachment 15:	Disclosure of Lobbying Activities, OMB Form SF-LLL	See attached PDF

INFORMATIONAL ATTACHMENTS

Attachment No.	Title	Location
Attachment 16:	Invoice Instructions for NIH Fixed Price Contracts NIH(RC)-2	http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/rc2_508.pdf
Attachment 17:	Invoice/Financing Request and Contract Financial Reporting Instructions--Cost Reimbursement, NIH(RC)-4	http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/rc4_508.pdf
Attachment 18:	Safety and Health, HHSAR Clause 352.223-70	See attached PDF
Attachment 19:	Sample Task Orders (19-1 to 19-5)	See attached PDFs

PART IV - REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST :

1. Go to the **System for Award Management (SAM)** and complete the Representations and Certifications. The SAM website may be accessed at: <http://www.sam.gov> ; and

2. Complete, and **INCLUDE as part of your BUSINESS PROPOSAL:**
SECTION K - REPRESENTATIONS, CERTIFICATIONS, AND OTHER STATEMENTS OF OFFERORS

which is included as an Attachment in Section J-LIST OF ATTACHMENTS, SOLICITATION ATTACHMENTS of this solicitation.

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

3. FAR Clause 52.204-19 **Incorporation by Reference of Representations and Certifications** (December 2014).

The Contractor's representations and certifications, including those completed electronically via the System for Award Management (SAM), are incorporated by reference into the contract.

(End of Clause)

SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

1. GENERAL INFORMATION

Offerors may submit WRITTEN questions requesting clarification of the Request for Proposal (RFP) contents. Information provided with each question must include the document name, specific page, paragraph, clause or other definitive citation requiring clarification. All questions must be submitted ELECTRONICALLY to Alexis Hudak at alexis.hudak@nih.gov. **FACSIMILE, TELEPHONE OR MAILED QUESTIONS WILL NOT BE ACCEPTED.**

Note: Questions must be received by March 7, 2016 at 2:00 PM Eastern Standard Time (EST) to allow NCI adequate time to prepare and issue an amendment prior to receipt of proposals. NCI will continue to accept questions up to the closing date and time for the RFP. HOWEVER, time may not permit responses to questions received after March 7, 2016 to be prepared and issued prior to receipt of proposals.

Sample Task Orders

Provide a response to each of the Sample Task Orders provided under **Attachment 19; numbered 19-1 through 19-5**. The response to the Sample Task Orders should be included as a separate section (appropriately marked) in the Technical Proposal. The Offeror's response to the Sample Task Orders should include discussion of technical approach, and personnel proposed. Please provide separate Cost Proposals addressing each of the task orders. Please submit a complete business proposal (i.e. including qualifying documentation, salary verification, supply price lists, etc) for Sample Task Order #1 only.

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

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

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

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

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

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

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

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

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

a. 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.

b. The first page of the proposal must show--

- i. The solicitation number;
- ii. The name, address, and telephone and facsimile numbers of the offeror (and electronic address if available);
- iii. A statement specifying the extent of agreement with all terms, conditions, and provisions included in the solicitation and agreement to furnish any or all items upon which prices are offered at the price set opposite each item;
- iv. Names, titles, and telephone and facsimile numbers (and electronic addresses if available) of persons authorized to negotiate on the offeror's behalf with the Government in connection with this solicitation; and
- v. Name, title, and signature of person authorized to sign the proposal. Proposals signed by an agent shall be accompanied by evidence of that agent's authority, unless that evidence has been previously furnished to the issuing office.

3. Submission, modification, revision, and withdrawal of proposals.

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

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

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

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

(3) It is the only proposal received.

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

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

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

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

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

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

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

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

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

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

(e) Restriction on disclosure and use of data.

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

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

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

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

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

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

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

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

(f) Contract award.

- (1) The Government intends to award a contract or contracts resulting from this solicitation to the responsible offeror(s) whose proposal(s) represents the best value after evaluation in accordance with the factors and subfactors in the solicitation.
- (2) The Government may reject any or all proposals if such action is in the Government's interest.
- (3) The Government may waive informalities and minor irregularities in proposals received.
- (4) The Government intends to evaluate proposals and award a contract without discussions with offerors (except clarifications as described in FAR 15.306(a)). Therefore, the offeror's initial proposal should contain the offeror's best terms from a cost or price and technical standpoint. The Government reserves the right to conduct discussions if the Contracting Officer later determines them to be necessary. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals.
- (5) The Government reserves the right to make an award on any item for a quantity less than the quantity offered, at the unit cost or prices offered, unless the offeror specifies otherwise in the proposal.
- (6) The Government reserves the right to make multiple awards if, after considering the additional administrative costs, it is in the Government's best interest to do so.
- (7) Exchanges with offerors after receipt of a proposal do not constitute a rejection or counteroffer by the Government.
- (8) The Government may determine that a proposal is unacceptable if the prices proposed are materially unbalanced between line items or subline items. Unbalanced pricing exists when, despite an acceptable total evaluated price, the price of one or more contract line items is significantly overstated or understated as indicated by the application of cost or price analysis techniques. A proposal may be rejected if the Contracting Officer determines that the lack of balance poses an unacceptable risk to the Government.
- (9) If a cost realism analysis is performed, cost realism may be considered by the source selection authority in evaluating performance or schedule risk.
- (10) A written award or acceptance of proposal mailed or otherwise furnished to the successful offeror within the time specified in the proposal shall result in a binding contract without further action by either party.
- (11) If a post-award debriefing is given to requesting offerors, the Government shall disclose the following information, if applicable:

 - (i) The agency's evaluation of the significant weak or deficient factors in the debriefed offeror's offer.
 - (ii) The overall evaluated cost or price and technical rating of the successful and debriefed offeror and past performance information on the debriefed offeror.
 - (iii) The overall ranking of all offerors, when any ranking was developed by the agency during source selection;
 - (iv) A summary of the rationale for award.
 - (v) For acquisitions of commercial items, the make and model of the item to be delivered by the successful offeror.
 - (vi) Reasonable responses to relevant questions posed by the debriefed offeror as to whether source-selection procedures set forth in the solicitation, applicable regulations, and other applicable authorities were followed by the agency.

(End of Provision)

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

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

b. NAICS CODE AND SIZE STANDARD

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

1. The North American Industry Classification System (NAICS) code for this acquisition is 541990.
2. The small business size standard is 15.0 million.

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

c. TYPE OF CONTRACT AND NUMBER OF AWARDS

1. It is anticipated that multiple awards will be made from this solicitation and that the awards will be made on/about July 1, 2016.
2. It is anticipated that the awards from this solicitation will be a multiple-year Indefinite Delivery/Indefinite Quantity type contracts with a five (5) year period of performance. Task Orders (TOs) issued under the contracts will be for non-severable components and will be either cost reimbursement or fixed price.
3. FAR 16.301-3 limits use of any contract type, other than firm-fixed price, to a contractor whose accounting system is adequate for determining costs applicable to the contract. To be considered for an award under this solicitation, the Offeror is required to certify, in its Business Proposal, the adequacy of its accounting system. See the paragraph entitled, Adequate Accounting System in Section L.2. Business Proposal Instructions in this solicitation for additional information about this certification.

d. TASK ORDERS UNDER MULTIPLE AWARD INDEFINITE DELIVERY CONTRACTS

a. General

The Contractor will be required provide services under the resultant contract only in performance of task orders and modifications to task orders signed by the Contracting Officer. Costs not attributed to the performance of a specific task order shall not be allowed without the prior written consent of the Contracting Officer. The Contractor will commence performance upon the receipt of a Task Order signed by the Contracting Officer. Costs for the preparation of Task Order proposals shall not be reimbursed as a direct cost under the resultant contract.

One or more task orders may be issued during the performance period of the resultant contract. If a contractor responds to a Task Order Request for Proposal (TORFP) and is the successful offeror, that Contractor will be required to accept and perform the task order issued by the Contracting Officer

within the scope of the resultant contract. The government has no obligation to issue any task orders, beyond the minimum identified in SECTION B of the contract. In the event of any inconsistency between any task order and the contract, the contract shall control.

In accordance with the Federal Acquisition Streamlining Act, the Contracting Officer will provide each Contractor a "Fair Opportunity" to be considered for each Task Order awarded in excess of \$3,000, unless one of the conditions in FAR 16.505(b)(2) applies.

The competition requirements in FAR Part 6, and the policies in FAR Subpart 15.3, **DO NOT APPLY** to the task ordering process. For each requirement under the resultant contract, the government intends to provide each Contractor a fair opportunity for consideration of a task order. The Contracting Officer shall:

1. Issue a notice of intent to award a task order for services to all resultant Contractors within a technical area covered by the task order requirement. To satisfy this requirement, the Contracting Officer will provide an e-mail notifying all qualified Contractors of the requirement. The e-mail will identify how the details concerning the requirement, including a description of the work and selection criteria, will be provided, i.e. attached to the e-mail, posted on a website. Contractors will be asked to submit a response to the notice of intent, advising the government of their intent to submit a proposal or quote;
2. Afford all Contractors, within the technical area covered by the task order requirement, who are responding to the notice, a fair opportunity to submit an offer and have that offer fairly considered;
3. Consider price and cost under each order as one of the factors in the selection decision;
4. Keep submission requirements to a minimum;
5. Consider past performance on earlier task orders under this contract to the maximum extent possible. Past performance considerations shall include, but not be limited to, the Contractor's performance regarding completeness, accuracy, clarity, timeliness and cost control. If a Contractor has no past performance on any earlier task order, past performance will be considered through other sources, such as the Contractor's original proposal.

In addition to the above, for all orders exceeding \$5 million, the Contracting Officer will consider all requirements set forth in FAR 16.505(b)(1)(iv).

a. Exceptions to Fair Opportunity

Contractors may not be given an opportunity to be considered for requirements in excess of \$3,000 if one of the following conditions applies:

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

b. Requesting Task Order Proposals

The Contracting Officer or a designated individual may solicit responses to requirements from Contractors within a technical area covered by a task order requirement in writing.

A Task Order Request for Proposals (TORFP) will be prepared and issued for each task order requirement. All contract clauses contained the resultant contract shall be incorporated in the TORFP and the resultant task order. If conflicts exist between the contract clauses and the information outlined in the task order, the resultant contract language takes precedence over the information in the task order.

c. Competitive Ordering Process

1. All Contractors within a technical area will receive e-mail notification advising of the availability of each proposed task order requirement. All proposed task orders will incorporate all terms of the resultant contract unless otherwise specified in the proposed task order.
2. Contractors will be provided an adequate time to prepare and submit responses based on the Contracting Officer's consideration of the estimated dollar value and complexity of proposed task order. Responses will not be considered a proposal as defined in FAR Part 15. However, the Contractor shall provide information sufficient for consideration in accordance with FAR Part 16. Each TORFP will indicate the criteria for the evaluation of proposals. The responses shall demonstrate capability for each criterion to be evaluated. Generally, the Contractor will be asked to demonstrate the following as appropriate:
 - Understanding of the requirements;
 - Experience and capability on similar tasks;
 - Technical approach, methods and procedures for satisfying the requirements with a discussion of potential problems to be encountered and proposed solutions and/or risk mitigation strategies.
 - Procedures for assuring quality of work, products, and deliverables;
 - Plan for managing the task order, including meeting requirements and schedules, and performance measures (if applicable);
 - Staffing plan with skill levels and level of effort for each individual proposed. Generally, resumes will be required for proposed personnel (if not previously submitted);
 - References to evaluate past performance; and
 - Cost/Price to perform the task order.

d. Evaluation and Award of Task Order Proposals

The Government will evaluate the Task Order proposals against the requirements of the TORFP. Specifically, the technical evaluation factors, cost/price, past performance and any other factor specifically identified in the TORFP will be used for evaluation of each proposal. In addition, the TORFP will identify the basis for selecting a contractor for award. Generally, technical factors will be significantly more important than price and other factors. However, each TORFP will specify how the award decision will be made.

Upon completion of evaluations, the Contracting Officer will issue a task order to the Contractor whose proposal is most advantageous to the government.

The Contracting Officer will notify the IDIQ Contractors of the selection decision in writing.

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. PROMOTING EFFICIENT SPENDING

On September 21, 2011, the Office of Management and Budget issued Memorandum M-11-35, entitled, "Eliminating Conference Spending and Promoting Efficiency in Government," emphasizing the President's priority to ensure that the Government operates with the utmost efficiency and eliminates unnecessary or wasteful spending. This was followed by the Executive Order on Delivering an Efficient, Effective, and Accountable Government (EO 13576) and the Executive Order on Promoting Efficient Spending (EO 13589).

On January 3, 2012, the Department of Health and Human Services (DHHS) issued the memorandum "HHS Policy on Promoting Efficient Spending: Use of Appropriated Funds for Conferences and Meetings, Food, Promotional Items, and Printing, and Publications" (See http://www.hhs.gov/asfr/ogapa/acquisition/effspendpol_memo.html).

In support of these directives, the NIH issued a January 30, 2012, Memorandum, entitled, "NIH Guidance Related to the HHS Policies on Promoting Efficient Spending: Use of Appropriated Funds for Conferences, Conference Grants and Meetings, Food, Promotional Items, and Printing and Publications." (See <http://oamp.od.nih.gov/>)

Any contract awarded as a result of this solicitation will:

- Specifically prohibit the use of contract funds for the provision of food for meals, light refreshments and beverages for any NIH funded meeting or conference; and
- Limit the procurement of meeting space, promotional items, printing and publications.

g. 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 SOLICITATIONS. Communications with other officials may compromise the competitiveness of this acquisition and result in cancellation of the requirement.

h. 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.

i. PREPARATION COSTS

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

j. SERVICE OF PROTEST (SEPTEMBER 2006) - FAR 52.233-2

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

Contracting Officer
Office of Acquisitions
National Cancer Institute
Riverside Five, 8490 Progress Drive, Ste 400
Frederick, Maryland, 21701-4998

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

(End of Provision)

2. INSTRUCTIONS TO OFFERORS

a. GENERAL INSTRUCTIONS

INTRODUCTION

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

1. Contract Type and General Clauses

It is contemplated that an Indefinite Delivery/Indefinite Quantity type contract will be awarded with cost reimbursement and fixed price task orders. (See General Information) Any resultant contract shall include the clauses applicable to the selected offeror's organization and type of contract awarded as required by Public Law, Executive Order, or acquisition regulations in effect at the time of execution of the proposed contract.

2. Authorized Official and Submission of Proposal

The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this RFP. Your proposal shall be submitted in the number of copies, to the addressees, and marked as indicated in the Attachment entitled, PACKAGING AND DELIVERY OF PROPOSAL, Part III, Section J hereof. Proposals will be typewritten, paginated, reproduced on letter size paper, printed/copied double-sided, on at least 30 percent post consumer fiber paper, as required by FAR 4.302(b), and will be legible in all required copies. To expedite the proposal evaluation, all documents required for responding to the SOLICITATION should be placed in the following order:

I. COVER PAGE

Include RFP title, number, name of organization, DUNS No., identification of the proposal part, and indicate whether the proposal is an original or a copy.

II. TECHNICAL PROPOSAL

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

III. BUSINESS PROPOSAL

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

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

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

4. Separation of Technical and Business Proposals

The proposal must be prepared in two parts: a "Technical Proposal" and a "Business Proposal." Each of the parts shall be separate and complete in itself so that evaluation of one may be accomplished

independently of, and concurrently with, evaluation of the other. The technical proposal must include direct cost and resources information, such as labor-hours and categories and applicable rates, materials, subcontracts, travel, etc., and associated costs so that the offeror's understanding of the project may be evaluated (See SECTION J, Attachment entitled, TECHNICAL PROPOSAL COST SUMMARY.) However, the technical proposal should not include pricing data relating to individual salary information, indirect cost rates or amounts, fee amounts (if any), and total costs. The technical proposal should disclose your technical approach in as much detail as possible, including, but not limited to, the requirements of the technical proposal instructions.

5. Alternate Proposals

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

6. Evaluation of Proposals

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

7. Potential Award Without Discussions

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

8. Use of the Metric System of Measurement

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

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

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

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

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

9. 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. 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 SOLICITATION pursuant to the authority provided by Sec. 301(a)(7) of the Public Health Service Act, as amended, and P.L. 92-218, as amended.

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

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

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

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

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

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

11. Selection of Offerors

- a. The acceptability of the technical portion of each contract proposal will be evaluated by a technical review committee. The committee will evaluate each proposal in strict conformity with the evaluation factors of the RFP, utilizing point scores and written critiques. The committee may suggest that the Contracting Officer request clarifying information from an offeror.
- b. The business portion of each contract proposal will be subjected to a cost and price analysis, management analysis, etc.
- c. If award will be made without conducting discussions, offerors may be given the opportunity to clarify certain aspects of their proposal (e.g., the relevance of an offeror's past performance

information and adverse past performance information to which the offeror has not previously had an opportunity to respond) or to resolve minor or clerical errors.

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

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

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

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

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

- e. The process described in FAR 15.101-1 will be employed, which permits the Government to make tradeoffs among cost or price and non-cost factors and to consider award to other than the lowest price offeror or other than the highest technically rated offeror.
- f. The NCI reserves the right to make a single award, multiple awards, or no award at all to the SOLICITATION. In addition, the SOLICITATION may be amended or canceled as necessary to meet NCI requirements. Synopses of awards exceeding \$25,000 will be published in FedBizOpps.

12. ROTC Access and Federal Military Recruiting on Campus

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

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

13. Certification of Filing and Payment of Taxes

None of the funds appropriated or otherwise made available by the Consolidated Appropriations Act of FY 2014, may be used to enter into a contract in an amount greater than \$5,000,000 unless

the prospective contractor certifies in writing to the agency awarding the contract that, to the best of its knowledge and belief, the contractor has filed all Federal tax returns required during the 3 years preceding the certification, has not been convicted of a criminal offense under the Internal Revenue Code of 1986, and has not, more than 90 days prior to certification, been notified of any unpaid Federal tax assessment for which the liability remains unsatisfied, unless the assessment is the subject of an installment agreement or offer in compromise that has been approved by the Internal Revenue Service and is not in default, or the assessment is the subject of a non-frivolous administrative or judicial proceeding.

14. Past Performance Information

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

A list of the last five (5) contracts completed during the past three years and ALL CONTRACTS currently being performed that are similar in nature to the solicitation workscope. Contracts listed may include those entered into by the Federal Government, agencies of state and local governments and commercial concerns. Offerors may also submit past performance information regarding predecessor companies, key personnel who have relevant experience or subcontractors that will perform major or critical aspects of the requirement when such information is relevant to the instant acquisition. For the purposes of this solicitation, a "major subcontract" is defined as a subcontract in excess of \$500,000.

Include the following information for each contract or subcontract listed:

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

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

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

15. Electronic and Information Technology Accessibility Notice, HHSAR 352.239-73 (December 2015)

a. Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998 and the Architectural and Transportation Barriers Compliance Board Electronic and Information (EIT) Accessibility Standards (36 CFR part 1194), require that when Federal agencies develop, procure, maintain, or use electronic and information technology, 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, unless an undue burden would be imposed on the agency. Section 508 also requires that individuals with disabilities, who are members of the public seeking information or services from a Federal agency, have access

to and use of information and data that is comparable to that provided to the public who are not individuals with disabilities, unless an undue burden would be imposed on the agency.

b. Accordingly, any offeror responding to this solicitation must comply with established HHS EIT accessibility standards. Information about Section 508 is available at <http://www.hhs.gov/web/508>. The complete text of the Section 508 Final Provisions can be accessed at <http://www.access-board.gov/guidelines-and-standards/communications-and-it/about-the-section-508-standards>.

c. The Section 508 accessibility standards applicable to this solicitation are stated in the clause at 352.239-74, Electronic and Information Technology Accessibility. In order to facilitate the Government's determination whether proposed EIT supplies meet applicable Section 508 accessibility standards, offerors must submit an HHS Section 508 Product Assessment Template, in accordance with its completion instructions. The purpose of the template is to assist HHS acquisition and program officials in determining whether proposed EIT supplies conform to applicable Section 508 accessibility standards. The template allows offerors or developers to self-evaluate their supplies and document-- in detail--whether they conform to a specific Section 508 accessibility standard, and any underway remediation efforts addressing conformance issues. Instructions for preparing the HHS Section 508 Evaluation Template are available under Section 508 policy on the HHS Web site <http://www.hhs.gov/web/508>. In order to facilitate the Government's determination whether proposed EIT services meet applicable Section 508 accessibility standards, offerors must provide enough information to assist the Government in determining that the EIT services conform to Section 508 accessibility standards, including any underway remediation efforts addressing conformance issues.

d. Respondents to this solicitation must identify any exception to Section 508 requirements. If a offeror claims its supplies or services meet applicable Section 508 accessibility standards, and it is later determined by the Government, i.e., after award of a contract or order, that supplies or services delivered do not conform to the described accessibility standards, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its expense.

(End of provision)

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

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.acquisition.gov/far/index.html>.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

a. Central Contractor Registration, FAR Provision 52.204-7 (July 2013).

Alternate I (July 2013) is not applicable to this solicitation.

b. Submission of Offers in the English Language, FAR Clause 52.214-34, (April 1991).

c. Submission of Offers in U.S. Currency, FAR Clause 52.214-35, (April 1991).

- d. Facilities Capital Cost of Money, FAR Clause 52.215-16, (June 2003).
- e. Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8, (October 1997).
- f. Limitations on Pass-Through Charges--Identification of Subcontract Effort, FAR Provision 52.215-22, (October 2009).
- g. Single or Multiple Awards, FAR Clause 52.216-27, (October 1995).

b. TECHNICAL PROPOSAL INSTRUCTIONS

OFFERORS SHOULD REFER TO ATTACHMENT 9 "ADDITIONAL TECHNICAL PROPOSAL INSTRUCTIONS" FOR ADDITIONAL INFORMATION AND THE SAMPLE TASK ORDER.

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

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

1. Technical Discussions

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

a. Statement of Work

1. Objectives

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

2. Approach

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

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

3. Methods

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

4. Schedule

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

b. Personnel

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

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

1. Single Principal Investigator/Project Director

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

2. Other Investigators

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

3. Additional Personnel

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

not meet this requirement. Commitment letters for use of consultants and other personnel to be hired must include:

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

4. Resumes

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

2. Other Considerations

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

- a. Any agreements and/or arrangements with subcontractor(s). Provide as much detail as necessary to explain how the statement of work will be accomplished within this working relationship.
- b. Unique arrangements, equipment, etc., which none or very few organizations are likely to have which is advantageous for effective implementation of this project.
- c. Equipment and unusual operating procedures established to protect personnel from hazards associated with this project.
- d. Other factors you feel are important and support your proposed research.
- e. Recommendations for changing reporting requirements if such changes would be more compatible with the offeror's proposed schedules.

3. Technical Evaluation

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

4. Care of Live Vertebrate Animals

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

Notice to Offerors of Requirement for Compliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals, HHSAR 352.270-5(a) (December 2015)

The Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (PHS Policy) establishes a number of requirements for research activities involving animals. Before awarding a contract to an offeror, the organization shall file, with the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), a written Animal Welfare Assurance (Assurance) which commits the organization to comply with the provisions of the PHS Policy, the Animal Welfare Act, and the Guide for the Care and Use of Laboratory Animals (National Academy Press, Washington, DC). In accordance with the PHS Policy, offerors must establish an Institutional Animal Care and Use Committee (IACUC), qualified through the experience and expertise of its members, to

oversee the institution's animal program, facilities, and procedures. Offerors must provide verification of IACUC approval prior to receiving an award involving live vertebrate animals. No award involving the use of animals shall be made unless OLAW approves the Assurance and verification of IACUC approval for the proposed animal activities has been provided to the Contracting Officer. Prior to award, the Contracting Officer will notify Contractor(s) selected for projects involving live vertebrate animals of the Assurance and verification of IACUC approval requirement. The Contracting Officer will request that OLAW negotiate an acceptable Assurance with those Contractor(s) and request verification of IACUC approval. For further information, contact OLAW at NIH, 6705 Rockledge Drive, RKL1, Suite 360, MSC 7982 Bethesda, Maryland 20892-7982 (Email: olaw@od.nih.gov; Phone: 301-496-7163).

(End of provision)

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

5. 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 Policy," (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://www.gpo.gov/fdsys/pkg/FR-1999-12-23/pdf/99-33292.pdf>

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

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

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

- a. Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998, and the Architectural and Transportation Barriers Compliance Board Electronic and Information (EIT) Accessibility Standards (36 CFR part 1194), require that, unless an exception applies, all EIT products and services developed, acquired, maintained, or used by any Federal department or agency permit—

- i. Federal employees with disabilities to have access to and use information and data that is comparable to the access and use of information and data by Federal employees who are not individuals with disabilities; and
 - ii. Members of the public with disabilities seeking information or services from a Federal agency to have access to and use of information and data that is comparable to the access and use of information and data by members of the public who are not individuals with disabilities.
- b. Accordingly, any vendor submitting a proposal/quotations/bid in response to this solicitation must demonstrate compliance with the established EIT accessibility standards. Information about Section 508 visions is available at <http://www.section508.gov/>. The complete text of Section 508 Final Provisions can be accessed at <http://www.access-board.gov/guidelines-and-standards>.
- c. The Section 508 accessibility standards applicable to this solicitation are identified in the Statement of Work/Specification/Performance Work Statement. In order to facilitate the Government's evaluation to determine whether EIT products and services proposed meet applicable Section 508 accessibility standards, offerors must prepare an HHS Section 508 Product Assessment Template, in accordance with its completion instructions, and provide a binding statement of conformance. The purpose of the template is to assist HHS acquisition and program officials in determining that EIT products and services proposed support applicable Section 508 accessibility standards. The template allows vendors or developers to self-evaluate their products or services and document in detail how they do or do not conform to a specific Section 508 standard. Instructions for preparing the HHS Section 508 Product Evaluation Template may be found on the HHS Web site (<http://www.hhs.gov/web/508/contracting/technology/vendors.html>).
- d. Respondents to this solicitation must also provide any additional detailed information necessary for determining applicable Section 508 standards conformance, as well as for documenting EIT products or services that are incidental to the project, which would constitute an exception to Section 508 requirements. If a vendor claims its products or services, including EIT deliverables such as electronic documents and reports, meet applicable Section 508 accessibility standards in its completed HHS Section 508 Product Assessment Template, and it is later determined by the Government -- i.e., after award of a contract/order, that products or services delivered do not conform to the described accessibility standards in the Product Assessment Template, remediation of the products or services to the level of conformance specified in the vendor's Product Assessment Template will be the responsibility of the Contractor and at its expense.

(End of provision)

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

c. BUSINESS PROPOSAL INSTRUCTIONS

1. Basic Cost/Price Information

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

2. Proposal Cover Sheet

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

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

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

3. Data Other than Certified Cost or Pricing Data

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

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

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

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

a. Direct Labor

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

b. Materials

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

c. Subcontracted Items

Include parts, components, assemblies, and services that are to be produced or performed by others in accordance with offeror's design, specifications, or direction and that are applicable only to the prime contract. For each subcontract over \$700,000, the support should provide a listing by source, item, quantity, price, type of subcontract, degree of competition, and basis for establishing source and reasonableness of price, as well as the results of review and evaluation of subcontract proposals when required by FAR 15.404-3.

d. Raw Materials

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

e. Purchased Parts

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

f. Fringe Benefits

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

g. Indirect Costs

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

h. Special Equipment

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

i. Travel

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

j. Other Costs

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

4. Salary Rate Limitation

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

This does not preclude the offeror from absorbing that portion of an employee's annual salary (plus the dollar amount for fringe benefits and associated indirect costs) that exceeds a rate of the Executive Schedule, Level II*. The Executive Schedule, Level II* annual salary rate limitation also applies to individuals proposed under subcontracts and to consultants. **LINK TO EXECUTIVE SCHEDULE RATES OF PAY:**

<https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/>

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

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

5. Small Business Subcontracting Plan

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

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

Business Concerns, and Service Disabled Veteran-Owned Small Business Concerns that each such aspect of the offeror's plan will be judged independent of the other.

6. The offeror will submit, as required by the Contracting Officer, subcontracting reports in accordance with the instructions thereon, and as further directed by the Contracting Officer. Subcontractors will also submit these reports to the Government's Contracting Officer or as otherwise directed, with a copy to the prime Contractor's designated small and disadvantaged business liaison.

d. Each plan must contain the following:

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

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

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

33% for Small Business; 5% for Small Disadvantaged Business; 5% for Women-Owned Small Business; 3% for HUBZone Small Business; and 3% for Veteran-Owned Small Business and Service-Disabled Veteran-Owned Small Business.

6. Mentor-Protégé Program, HHSAR 352.219-70 (December) 2015

a. Large business prime contractors serving as mentors in the HHS Mentor-Protege Program are eligible for HHS subcontracting plan credit, and shall submit a copy of their HHS Office of Small and Disadvantaged Business Utilization (OSDBU) approved mentor-protege agreements as part of their offers. The amount of credit provided by the Contracting Officer to a mentor firm for protege firm developmental assistance costs shall be calculated on a dollar for dollar basis and reported by the mentor firm in the Summary Subcontract Report via the Electronic Subcontracting Reporting System (eSRS) at www.esrs.gov. The mentor firm and protege firm shall submit to the Contracting Officer a signed joint statement agreeing on the dollar value of the developmental assistance the mentor firm provided. (For example, a mentor firm would report a \$10,000 subcontract awarded to a protege firm and provision of \$5,000 of developmental assistance as \$15,000 of subcontracting plan credit.) The mentor firm may use this additional credit towards attaining its subcontracting plan participation goal under this contract.

b. The program consists of--

1. Mentor firms--large businesses that:
 - (i) Demonstrate the interest, commitment, and capability to provide developmental assistance to small business protégé firms; and
 - (ii) Have a Mentor-Protege agreement approved by HHS' OSDBU;
 2. Protege firms--firms that:
 - (i) Seek developmental assistance;
 - (ii) Qualify as small businesses, veteran-owned small businesses, service-disabled veteran-owned small businesses, HUBZone small businesses, small disadvantaged businesses, or woman-owned small businesses; and
 - (iii) Have a Mentor-Protege agreement approved by HHS' OSDBU; and
 3. Mentor-Protege agreements--joint agreements, approved by HHS' OSDBU, which detail the specific terms, conditions, and responsibilities of the mentor-protégé relationship.
- (End of provision)

7. HUBZone Small Business Concerns

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

8. Total Compensation Plan

a. Instructions

1. Total compensation (salary and fringe benefits) of professional employees under service contracts may, in some cases, be lowered by recompetition of these contracts. Lowering of compensation can be detrimental in obtaining the necessary quality of professional services needed for adequate performance of service contracts. It is, therefore, in the

best interest of the Government that professional employees, as defined in 29 CFR Part 541, be properly compensated in these contracts. All offerors as a part of their Business Proposal will submit a "Total Compensation Plan" (salaries and fringe benefits) for these professional employees for evaluation purposes.

2. The Government will evaluate the Total Compensation Plan to ensure that this compensation reflects a sound management approach and an understanding of the requirements to be performed. It will include an assessment of the offeror's ability to provide uninterrupted work of high quality. The total compensation proposed will be evaluated in terms of enhancing recruitment and retention of personnel and its realism and consistency with a total plan for compensation (both salaries and fringe benefits).
3. Evaluation for award, therefore, will include an assessment of the Total Compensation Plan submitted by each offeror.

b. Evaluation

1. Total Compensation Plan (Professional Employees)

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

2. Cost (Professional Compensation)

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

3. Other (Labor Relations)

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

4. Federal Acquisition Regulation Clauses incorporated by Reference

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

9. Other Administrative Data

a. Property

1. It is HHS policy that Contractors will provide all property necessary for contract performance. Exception may be granted to provide Government property (Government-furnished or Contractor-acquired), but only when approved by the Contracting Officer. If the offeror requests that Government property be provided, other than that specified under "Government Furnished Property," below, the proposal must include a comprehensive justification addressing the following items:
 - a. State why the property is essential to contract performance and whether the property will be used exclusively for this contract.
 - b. Describe other alternatives (e.g., purchase, lease, etc.) pursued and why they were not viable options.

2. Government Property

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

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

NOTE: The Contracting Officer will consider any potentially unfair competitive advantage that may result from an offeror or contractor possessing Government property. This will be done by adjusting the offers by applying, for evaluation purposes only, a rental equivalent evaluation factor, as specified in FAR 52.245-9.

3. Government-Furnished Property

No Government Furnished Property is offered for this acquisition

4. The management and control of any Government property shall be in accordance with the HHS Publication entitled, "HHS Contracting Guide for Contract of Government Property," which can be found at: <https://web.archive.org/web/20111015044731/http://www.hhs.gov/hhsmanuals/>.

b. Submission of Electronic Funds Transfer Information with Offer, FAR Clause 52.232-38 (JULY 2013)

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 System for Award Management.

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

(End of Provision)

c. Financial Capacity

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

d. Adequate Accounting System

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

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

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

- Complies with generally accepted accounting principles (GAAP).
- Provides for:
 - Proper segregation of direct costs from indirect costs.
 - Identification and accumulation of direct costs by contract.
 - A logical and consistent method for the allocation of indirect costs to intermediate and final cost objectives.
 - Accumulation of costs under general ledger control.

- A timekeeping system that identifies employees' labor by intermediate or final cost objectives.
- A labor distribution system that charges direct and indirect labor to the appropriate cost objectives.
- Interim (at least monthly) determination of costs charged to a contract through routine posting of books of account.
- Exclusion from costs charged to government contracts of amounts that are not allowable in terms of FAR 31, "Contract Cost Principles and Procedures," or other contract provisions.
- Identification of costs by contract line item and by units (as if each unit or line item were a separate contract) if required by the proposed contract.
- Segregation of preproduction costs from production costs, if applicable.
- Accounting system provides financial information:
 - Required by contract clause concerning limitation of cost (FAR 52.232-20) or limitation on payments (FAR 52.216-16).
 - Required to support requests for progress payments.
- Accounting system was designed, and records are maintained in such a manner that adequate, reliable data are developed for use in pricing follow-on acquisitions.
- Accounting system is currently in full operation.

The Contracting Officer reserves the right to request, with the Final Proposal Revision (FPR), a current (within 18 months) CPA opinion confirming that the Offeror's accounting system is compliant as certified above.

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

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

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

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

(End of Provision)

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

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

Fac Cap Cost of Money (Has Not) 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. 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.

11. 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.

12. Proposer's Annual Financial Report

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

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

1. GENERAL

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

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

2. COST/PRICE EVALUATION

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

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

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

3. EVALUATION OF OPTIONS

It is anticipated that any contract(s) awarded from this solicitation will contain option provision(s) and period(s).

In accordance with FAR Clause 52.217-5, Evaluation of Options, (July 1990), the Government will evaluate offers for award purposes by adding the total price for all options to the total price for the basic requirement, except when it is determined in accordance with FAR 17.206(b) not to be in the Government's best interests. Evaluation of options will not obligate the Government to exercise the option(s).

4. EVALUATION OF DATA SHARING PLAN

The offeror's plan for the sharing of final research data, or, if data sharing is not possible, the offeror's documentation of its inability to share research data, shall be assessed for appropriateness and adequacy.

5. TECHNICAL EVALUATION FACTORS

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

A. PERSONNEL: Weight 30 Points

- Availability and qualifications of a Project Director/Project Manager with demonstrated leadership experience in managing an interdisciplinary team in the conduct of pharmacokinetic and other pharmacological investigations of therapeutic agents.
- Adequacy and suitability of the Project Director/Project Manager's scientific training and experience appropriate for leading this project as evidenced by his/her bibliography and Curriculum Vitae, a list of study reports authored, and other unpublished manuscripts.
- Training, experience, and qualifications of other personnel to perform the tasks outlined in the Statement of Work (SOW) (e.g., analytical chemistry, pharmacokinetics, drug metabolism, pharmacodynamic methods, laboratory animal care, etc.).
- Extent that the proposed personnel have previously worked together as a team on projects equivalent to those described in the SOW.

B. TECHNICAL APPROACH AND AWARENESS OF THE PROBLEM: Weight 30 Points

- Demonstration of a sound understanding of the established analytical methods/protocols to implement and validate procedures in relation to the intended purpose of the study being performed and the stage of the compound(s) in the drug development process.
- Evidence of a rational approach to the collection, analysis, and modeling of pharmacokinetic data in animals, as evidenced by the examples given in the proposal.
- Evidence of a sound understanding of drug metabolism and the methodologies used to identify putative drug metabolites in biological samples.
- Understanding of the problems likely to be encountered when conducting such evaluations, and their solution, as demonstrated by first-hand experience with diverse types of agents and preclinical models.

C. FACILITIES AND EQUIPMENT: Weight 30 Points

- Availability and accessibility of suitable laboratory space, equipment, and animal facilities to carry out the SOW, including capacity for multiple evaluations that be run simultaneously.
- Availability and adequacy of major equipment such as liquid chromatography tandem mass spectrometry (LC-MS) systems, Gas Chromatography (GC), and Nuclear Magnetic Resonance (NMR), and other laboratory instrumentation.
- Adequacy and availability of computing, software, and electronic information and/or library resources.

D. Organizational Experience and Support/Safety & Security: Weight 10 Points

- Extent and significance of organizational accomplishments in areas covered by the SOW.
- Evidence of the organization's ability to provide appropriate personnel, resources, and capacity to carry out the work and submit deliverables (reports) in an expeditious manner.
- Ability of the organization to handle (technically and administratively) varying levels of assigned work, including simultaneous projects or periods with no active scientific projects).
- Adequacy of the safety and security procedures to be used in conducting the proposed work.

TOTAL: 100 points

6. EVALUATION OF ELECTRONIC AND INFORMATION TECHNOLOGY ACCESSIBILITY - SECTION 508

The offeror's proposal must demonstrate compliance with the "Electronic and Information Technology Accessibility Provisions" set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the "Access Board") in 36 CFR part 1194 for all electronic and information technology (EIT) products and services developed, acquired, maintained, or used under this contract/order, including EIT deliverables such as electronic documents and reports.

If your proposal does not include a completed HHS "Section 508 Product Assessment Template" (hereafter referred to as the "Template") which demonstrates that EIT products and services proposed support applicable Section 508 accessibility standards, or, if the completed "Template" included in your proposal is considered "noncompliant," and the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to further discuss, clarify or modify the "Template" during discussions and in your Final Proposal Revision (FPR). If your "Template" is still considered "noncompliant" by the Government after discussions, your proposal may not be considered further for award.

7. PAST PERFORMANCE FACTOR

Offeror's past performance information will be evaluated subsequent to the technical evaluation. However, this evaluation will not be conducted on any offeror whose proposal is determined to be technically unacceptable.

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

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

When assessing performance risks, the Government, to the fullest extent practicable, will focus on the past performance of the offeror as it relates to all acquisition requirements, in terms of Quality, Schedule, Cost Control, Business Relations, Management, Small Business and Other factors as deemed appropriate.

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

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

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. N02CM67000-11

DUE DATE: March 22, 2016 at 2:00 PM (Eastern Standard Time)

TO BE OPENED BY AUTHORIZED GOVERNMENT PERSONNEL ONLY

PLEASE READ THE FOLLOWING INFORMATION CAREFULLY:

NUMBER OF COPIES

TECHNICAL PROPOSAL: **ORIGINAL* AND TEN (10) COPIES TO:**

BUSINESS PROPOSAL: **ORIGINAL* AND FIVE (5) COPIES TO:**

If hand-delivered, delivery service or U.S. Postal Service

Alexis Hudak, Contracting Officer
Office of Acquisitions
National Cancer Institute
Riverside Five, Ste 400, Room 4037
Frederick, Maryland 21701-4998

NOTE: Riverside Five is a secure building/suite. For directions to Riverside Five, please refer to the following website <http://www.riversidefive.com/> for (Map & Directions). It is the responsibility of the offeror to ensure that sufficient time is allotted to enter Riverside Five, Suite 400 locate and deliver your proposal prior to the date and time specified for receipt of proposals. It is recommended that you contact Alexis Hudak on 301-624-8753 to schedule a specific date/time in order to deliver your proposal.

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

NOTE: The Government is not responsible for picking up any mail at the local post office. It is the offeror's responsibility to allow sufficient time for security clearance at the main gate and then delivery of the proposal to the designated location by the date and time for receipt of proposals.

RFP Number: N02CM67000-11
Attachment 1:

If a proposal is not received at the place, date, and time specified herein, it will be considered a "late proposal."

Attachment 1

December 20, 2015

Statement of Work
“Preclinical Pharmacokinetic and Pharmacology Evaluations of
Agents Being Developed for Cancer Patients.”

- A. Independently and not as an agent of the Government, the Contractor shall furnish all of the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as required to perform the work stated below in accordance with protocols to be developed by the National Cancer Institute’s (NCI) Contracting Officer Representative (COR).

Compounds under evaluation will vary in their stage of development and in their requirements for evaluation. Therefore, Task Orders specific for each compound will be developed by the COR and the Contractor shall perform one or more of the following:

1. Implement and validate COR-designated analytical methods that are sufficiently sensitive, specific, and reproducible for measurement and quantitation of assigned test agents (e.g., small molecule therapeutics and well-characterized biologicals) and metabolites in body fluids and/or tissues of animals and humans at therapeutic and/or toxic concentrations.
2. Conduct pharmacokinetic evaluations in animals (e.g., mice, rats, tumor-bearing rodents, optionally larger animals) to support early lead and candidate drug characterization. Various routes of administration (e.g., intravenous, oral, intraperitoneal, subcutaneous, continuous infusion, etc.) may be utilized. Evaluations may include collection of multiple blood samples to obtain plasma or serum and, in some evaluations, collection of urine, feces, tissues or tumor samples. Detailed protocols will be provided by the COR.
3. Utilize established analytical methods/protocols to determine concentrations of test agents in various matrices (cell extracts, media, plasma, urine, bile, saliva, tumors, and normal tissues) that may be derived from:
 - (a) Pharmacokinetic evaluations conducted under item 2 above;
 - (b) Other Government-sponsored laboratories
 - (c) Human clinical trials
4. Use state-of-the-art modeling software to fit concentration vs. time data (for plasma and possibly tissues) to suitable non-compartmental and/or compartmental pharmacokinetic models and calculate relevant pharmacokinetic parameters (e.g., half-life, volume of distribution, area under the curve, clearance, etc.) for a given agent and route of administration.
5. Calculate systemic bioavailability for various routes (e.g., oral, ip, sc) and determine if bioavailability is dose-dependent. Calculate mass-balance parameters when sufficient data are collected.

December 20, 2015

6. Determine the suitability of standard formulation strategies for the administration of test agents to animals by the desired route and at the desired dose level(s).
7. Determine the *in vitro* plasma protein binding and stability of test agents in biological fluids and tissues using standard techniques.
8. Carry out Pharmacokinetic-Pharmacodynamic (PK-PD) evaluation protocols (developed by the COR) in tumor-bearing mice and collect plasma, tissue, and/or tumor samples for drug level determinations and analysis of specified pharmacodynamic endpoints.
9. Utilize standard mass spectroscopic techniques to characterize the metabolites and/or degradation products of test agents present in blood, plasma, urine, and/or other fluids. The extent of metabolite characterization will be specified by the NCI COR.
10. Store samples generated in-house or received from other laboratories under suitable conditions and ship samples to other laboratories upon request by the NCI COR.

B. SAMPLE TASK ORDERS

Sample Task Order Requests to be included in the solicitation are specified below:

1. Pharmacokinetic and Bioavailability Evaluations of Anticancer Compounds in Mice.
2. Pharmacokinetic-Pharmacodynamic-Efficacy Evaluations of Anticancer Compounds in Tumor-Bearing Mice.
3. Analytical Support for Pharmacology Evaluations with Selected Anticancer Agents
4. Determination of [NSC – to be determined] in Plasma and Urine Samples from an NCI-supported Human Phase I Clinical Trial.
5. Kick-off Meeting with NCI Staff

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

Updated through FAC
2005-86
Last updated: 01/2016

This SECTION is made up of six parts as follows:

1. Annual Representations and Certifications, FAR 52.204-8
2. Commercial and Government Entity Code Reporting, FAR 52.204-16
3. Information Regarding Responsibility Matters, FAR 52.209-7
4. Cost Accounting Standards
5. Certification Regarding Environmental Tobacco Smoke
6. Certification of Institutional on Financial Conflicts of Interest
7. Disaster or Emergency Area Representation
8. Alternate – Representation by Corporations Regarding an Unpaid Delinquent Tax Liability or a Felony Conviction Under Any Federal Law

To Be Completed by the Offeror: This document must be completed and included as part of your Business Proposal. By submission of its signed offer, the offeror makes the following Representations and Certifications:

1. ANNUAL REPRESENTATIONS AND CERTIFICATIONS (JAN 2016), FAR Provision 52.204-8

- (a) (1) The North American Industry Classification System (NAICS) code for this acquisition is _____ *[insert NAICS code]*.
- (2) The Small Business Size Standard is _____ *[insert size standard]*.
- (3) The small business size standard for a concern which submits an offer in its own name, other than on a construction or service contract, but which proposes to furnish a product which it did not itself manufacture, is 500 employees.
- (b) (1) If the provision at 52.204-7, System for Award Management, is included in this solicitation, paragraph (d) of this provision applies.
- (2) If the provision at 52.204-7 is not included in this solicitation, and the offeror is currently registered in System for Award Management (SAM), and Representations and Certifications section of SAM has completed the Representations and Certifications section of SAM electronically, the offeror may choose to use paragraph (d) of this provision instead of completing the corresponding individual representations and certifications in the solicitation. The offeror shall indicate which option applies by checking one of the following boxes:
- (i) Paragraph (d) applies.
- (ii) Paragraph (d) does not apply and the offeror has completed the individual representations and certifications in the solicitation. *[See Individual Representations and Certifications]*
- (c) (1) The following representations or certifications in SAM are applicable to this solicitation as indicated:
- (i) 52.203-2, Certificate of Independent Price Determination. This provision applies to solicitations when a firm-fixed-price contract or fixed-price contract with economic price adjustment is contemplated, unless—

- (A) The acquisition is to be made under the simplified acquisition procedures in Part 13;
 - (B) The solicitation is a request for technical proposals under two-step sealed bidding procedures; or
 - (C) The solicitation is for utility services for which rates are set by law or regulation.
- (ii) 52.203-11, Certification and Disclosure Regarding Payments to Influence Certain Federal Transactions. This provision applies to solicitations expected to exceed \$150,000.
- (iii) 52.204-3, Taxpayer Identification. This provision applies to solicitations that do not include the provision at 52.204-7, System for Award Management.
- (iv) 52.204-5, Women-Owned Business (Other Than Small Business). This provision applies to solicitations that—
- (A) Are not set aside for small business concerns;
 - (B) Exceed the simplified acquisition threshold; and
 - (C) Are for contracts that will be performed in the United States or its outlying areas.
- (v) 52.209-2, Prohibition on Contracting with Inverted Domestic Corporations—Representation.
- (vi) 52.209-5, Certification Regarding Responsibility Matters. This provision applies to solicitations where the contract value is expected to exceed the simplified acquisition threshold.
- (vii) 52.214-14, Place of Performance--Sealed Bidding. This provision applies to invitations for bids except those in which the place of performance is specified by the Government.
- (viii) 52.215-6, Place of Performance. This provision applies to solicitations unless the place of performance is specified by the Government.
- (ix) 52.219-1, Small Business Program Representations (Basic & Alternate I). This provision applies to solicitations when the contract will be performed in the United States or its outlying areas.
- (A) The basic provision applies when the solicitations are issued by other than DoD, NASA, and the Coast Guard.
 - (B) The provision with its Alternate I applies to solicitations issued by DoD, NASA, or the Coast Guard.
- (x) 52.219-2, Equal Low Bids. This provision applies to solicitations when contracting by sealed bidding and the contract will be performed in the United States or its outlying areas.
- (xi) 52.222-22, Previous Contracts and Compliance Reports. This provision applies to solicitations that include the clause at 52.222-26, Equal Opportunity.

- (xii) 52.222-25, Affirmative Action Compliance. This provision applies to solicitations, other than those for construction, when the solicitation includes the clause at 52.222-26, Equal Opportunity.
 - (xiii) 52.222-38, Compliance with Veterans' Employment Reporting Requirements. This provision applies to solicitations when it is anticipated the contract award will exceed the simplified acquisition threshold and the contract is not for acquisition of commercial items.
 - (xiv) 52.223-1, Biobased Product Certification. This provision applies to solicitations that require the delivery or specify the use of USDA-designated items; or include the clause at 52.223-2, Affirmative Procurement of Biobased Products Under Service and Construction Contracts.
 - (xv) 52.223-4, Recovered Material Certification. This provision applies to solicitations that are for, or specify the use of, EPA-designated items.
 - (xvi) 52.225-2, Buy American Certificate. This provision applies to solicitations containing the clause at 52.225-1.
 - (xvii) 52.225-4, Buy American--Free Trade Agreements--Israeli Trade Act Certificate. (Basic, Alternates I, II, and III.) This provision applies to solicitations containing the clause at 52.225-3.
 - (A) If the acquisition value is less than \$25,000, the basic provision applies.
 - (B) If the acquisition value is \$25,000 or more but is less than \$50,000, the provision with its Alternate I applies.
 - (C) If the acquisition value is \$50,000 or more but is less than \$77,533, the provision with its Alternate II applies.
 - (D) If the acquisition value is \$77,533 or more but is less than \$100,000, the provision with its Alternate III applies.
 - (xviii) 52.225-6, Trade Agreements Certificate. This provision applies to solicitations containing the clause at 52.225-5.
 - (xix) 52.225-20, Prohibition on Conducting Restricted Business Operations in Sudan--Certification. This provision applies to all solicitations.
 - (xx) 52.225-25, Prohibition on Contracting with Entities Engaging in Certain Activities or Transactions Relating to Iran--Representation and Certification. This provision applies to all solicitations.
 - (xxi) 52.226-2, Historically Black College or University and Minority Institution Representation. This provision applies to solicitations for research, studies, supplies, or services of the type normally acquired from higher educational institutions.
- (2) The following certifications are applicable as indicated by the Contracting Officer: *[Contracting Officer check as appropriate.]*
- (i) 52.204-17, Ownership or Control of Offeror
 - (ii) 52.222-18, Certification Regarding Knowledge of Child Labor for Listed End Products.

- (iii) 52.222-48, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment Certification.
- (iv) 52.222-52 Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services--Certification.
- (v) 52.223-9, with its Alternate I, Estimate of Percentage of Recovered Material Content for EPA-Designated Products (Alternate I only).
- (vi) 52.227-6, Royalty Information.
 - (A) Basic.
 - (B) Alternate I.
- (vii) 52.227-15, Representation of Limited Rights Data and Restricted Computer Software.

(d) The offeror has completed the annual representations and certifications electronically via the SAM website accessed through <https://www.acquisition.gov>. After reviewing the SAM database information, the offeror verifies by submission of the offer that the representations and certifications currently posted electronically that apply to this solicitation as indicated in paragraph (c) of this provision have been entered or updated within the last 12 months, are current, accurate, complete, and applicable to this solicitation (including the business size standard applicable to the NAICS code referenced for this solicitation), as of the date of this offer and are incorporated in this offer by reference (see FAR 4.1201); except for the changes identified below [*offeror to insert changes, identifying change by clause number, title, date*]. These amended representation(s) and/or certification(s) are also incorporated in this offer and are current, accurate, and complete as of the date of this offer.

FAR Clause No.	Title	Date	Change

Any changes provided by the offeror are applicable to this solicitation only, and do not result in an update to the representations and certifications posted on SAM.

(End of Provision)

2. **COMMERCIAL AND GOVERNMENT ENTITY CODE REPORTING, (JUL 2015) FAR Provision 52.204-16**

Note to Offeror: This provision is incorporated by reference and is applicable when the resultant contract will contain FAR Provision 52.204-6 and/or FAR Provision 52.204-7.

3. **INFORMATION REGARDING RESPONSIBILITY MATTERS, (JUL 2013) FAR Provision 52.209-7**

Note to Offeror: This provision is applicable when the resultant contract is expected to exceed \$500,000.

(a) Definitions. As used in this provision—

Administrative proceeding means a non-judicial process that is adjudicatory in nature in order to make a determination of fault or liability (e.g., Securities and Exchange Commission Administrative proceedings, Civilian Board of Contract Appeals Proceedings, and Armed Services Board of Contract Appeals Proceedings). This includes administrative proceedings at the Federal and State level but only in connection with performance of a Federal contract or grant. It does not include agency actions such as contract audits, site visits, corrective plans, or inspection of deliverables.

Federal contracts and grants with total value greater than \$10,000,000 means--

- (1) The total value of all current, active contracts and grants, including all priced options; and
- (2) The total value of all current, active orders including all priced options under indefinite-delivery, indefinite-quantity, 8(a), or requirements contracts (including task and delivery and multiple-award Schedules).

Principal means an officer, director, owner, partner, or a person having primary management or supervisory responsibilities within a business entity (e.g., general manager; plant manager; head of a division or business segment; and similar positions).

(b) The offeror has does not have current active Federal contracts and grants with total value greater than \$10,000,000.

(c) If the offeror checked “has” in paragraph (b) of this provision, the offeror represents, by submission of this offer, that the information it has entered in the Federal Awardee Performance and Integrity Information System (FAPIIS) is current, accurate, and complete as of the date of submission of this offer with regard to the following information:

- (1) Whether the offeror, and/or any of its principals, has or has not, within the last five years, in connection with the award to or performance by the offeror of a Federal contract or grant, been the subject of a proceeding, at the Federal or State level that resulted in any of the following dispositions:
 - (i) In a criminal proceeding, a conviction.
 - (ii) In a civil proceeding, a finding of fault and liability that results in the payment of a monetary fine, penalty, reimbursement, restitution, or damages of \$5,000 or more.

(iii) In an administrative proceeding, a finding of fault and liability that results in—

- (A) The payment of a monetary fine or penalty of \$5,000 or more; or
- (B) The payment of a reimbursement, restitution, or damages in excess of \$100,000.

(iv) In a criminal, civil, or administrative proceeding, a disposition of the matter by consent or compromise with an acknowledgment of fault by the Contractor if the proceeding could have led to any of the outcomes specified in paragraphs (c)(1)(i), (c)(1)(ii), or (c)(1)(iii) of this provision.

(2) If the offeror has been involved in the last five years in any of the occurrences listed in (c)(1) of this provision, whether the offeror has provided the requested information with regard to each occurrence.

(d) The offeror shall post the information in paragraphs (c)(1)(i) through (c)(1)(iv) of this provision in FAPIIS as required through maintaining an active registration in the System for Award Management database at www.acquisition.gov (see 52.204-7).

COST ACCOUNTING STANDARDS

4. Cost Accounting Standards Notices and Certification (October 2015), FAR Provision 52.230-1

Note: This notice does not apply to small businesses or foreign governments. This notice is in three parts, identified by Roman numerals I through III.

Offerors shall examine each part and provide the requested information in order to determine Cost Accounting Standards (CAS) requirements applicable to any resultant contract.

If the offeror is an educational institution, Part II does not apply unless the contemplated contract will be subject to full or modified CAS-coverage pursuant to 48 CFR 9903.201-2(C)(5) or 9903.201-2(c)(6), respectively.

(I) Disclosure Statement -- Cost Accounting Practices and Certification

- (a) Any contract in excess of \$750,000 resulting from this solicitation will be subject to the requirements of the Cost Accounting Standards Board (48 CFR Chapter 99), except for those contracts which are exempt as specified in 9903.201-1.
- (b) Any offeror submitting a proposal which, if accepted, will result in a contract subject to the requirements of 48 CFR Chapter 99 must, as a condition of contracting, submit a Disclosure Statement as required by 9903.202. When required, the Disclosure Statement must be submitted as a part of the offeror's proposal under this solicitation unless the offeror has already submitted a Disclosure Statement disclosing the practices used in connection with the pricing of this proposal. If an applicable Disclosure Statement has already been submitted, the offeror may satisfy the requirement for submission by providing the information requested in paragraph (c) of Part I of this

provision.

CAUTION: In the absence of specific regulations or agreement, a practice disclosed in a Disclosure Statement shall not, by virtue of such disclosure, be deemed to be a proper, approved, or agreed-to practice for pricing proposals or accumulating and reporting contract performance cost data.

(c) Check the appropriate box below:

(1) Certificate of Concurrent Submission of Disclosure Statement.

The offeror hereby certifies that, as part of the offer, copies of the Disclosure Statement have been submitted as follows:

- i original and one copy to the cognizant Administrative Contracting Officer (ACO), or cognizant Federal agency official authorized to act in that capacity (Federal official), as applicable, and;
- ii one copy to the cognizant Federal auditor.

(Disclosure must be on Form No. CASB DS-1 or CASB DS-2, as applicable.. Forms may be obtained from the cognizant ACO or Federal official and/or from the looseleaf version of the Federal Acquisition Regulation).

Date of Disclosure Statement: _____

Name and Address of Cognizant ACO or Federal Official Where Filed:

The offeror further certifies that the practices used in estimating costs in pricing this proposal are consistent with the cost accounting practices disclosed in the Disclosure Statement.

(2) Certificate of Previously Submitted Disclosure Statement.

The offeror hereby certifies that the required Disclosure Statement was filed as follows:

Date of Disclosure Statement:

Name and Address of Cognizant ACO or Federal Official Where Filed:

The offeror further certifies that the practices used in estimating costs in pricing this proposal are consistent with the cost accounting practices disclosed in the applicable Disclosure Statement.

(3) Certificate of Monetary Exemption.

The offeror hereby certifies that the offeror together with all divisions, subsidiaries, and affiliates under common control, did not receive net awards of negotiated prime contracts and subcontracts subject to CAS totaling more than \$50 million or more in the cost accounting period immediately preceding the period in which this proposal was submitted. The offeror further certifies that if such status changes before an award resulting from this proposal, the offeror will advise the Contracting Officer immediately.

(4) Certificate of Interim Exemption.

The offeror hereby certifies that:

- i the offeror first exceeded the monetary exemption for disclosure, as defined in (3) of this subsection, in the cost accounting period immediately preceding the period in which this offer was submitted, and
- ii in accordance with 48 CFR 9903.202-1, the offeror is not yet required to submit a Disclosure Statement. The offeror further certifies that if an award resulting from this proposal has not been made within 90 days after the end of that period, the offeror will immediately submit a revised certificate to the Contracting Officer, in the form specified under subparagraph (c)(1) or (c)(2) of Part I of this provision, as appropriate, to verify submission of a completed Disclosure Statement.

CAUTION: Offerors currently required to disclose because they were awarded a CAS-covered prime contract or subcontract of \$50 million or more in the current cost accounting period may not claim this exemption (4). Further, the exemption applies only in connection with proposals submitted before expiration of the 90-day period following the cost accounting period in which the monetary exemption was exceeded.

(II) Cost Accounting Standards—Eligibility for Modified Contract Coverage

If the offeror is eligible to use the modified provisions of 48 CFR 9903.201-2(b) and elects to do so, the offeror shall indicate by checking the box below. Checking the box below shall mean that the resultant contract is subject to the Disclosure and Consistency of Cost Accounting Practices clause in lieu of the Cost Accounting Standards clause.

The offeror hereby claims an exemption from the Cost Accounting Standards clause under the provisions of 48 CFR 9903.201-2(b) and certifies that the offeror is eligible for use of the Disclosure and Consistency of Cost Accounting Practices clause because during the cost accounting period immediately preceding the period in which this proposal was submitted, the offeror received less than \$50 million in awards of CAS-covered prime contracts and subcontracts. The offeror further certifies that if such status changes before an award resulting from this proposal, the offeror will advise the Contracting Officer immediately.

CAUTION: An offeror may not claim the above eligibility for modified contract coverage if this proposal is expected to result in the award of a CAS-covered contract of \$50 million or more or if, during its current cost accounting period, the offeror has been awarded a single CAS-covered prime contract or subcontract of \$50 million or more.

(III) Additional Cost Accounting Standards Applicable to Existing Contracts

The offeror shall indicate below whether award of the contemplated contract would, in accordance with subparagraph (a)(3) of the Cost Accounting Standards Clause, require a change in established cost accounting practices affecting existing contracts and subcontracts.

YES NO

(2) Proposal Disclosure-Cost Accounting Practice Changes, (March 2005)(FAR Provision 52.230-7)

The offeror shall check "yes" below if the contract award will result in a required or unilateral change in cost accounting practice, including unilateral changes requested to be desirable changes.

YES NO

If the offeror checked "Yes" above, the offeror shall—

- (1) Prepare the price proposal in response to the solicitation using the changed practice for the period of performance for which the practice will be used; and
- (2) Submit a description of the changed cost accounting practice to the Contracting Officer and the Cognizant Federal Agency Official as pricing support for the proposal.

5. CERTIFICATION REGARDING ENVIRONMENTAL TOBACCO SMOKE (December 1994)

Public Law 103-227, also known as the Pro-Children Act of 1994 (Act), requires that smoking not be permitted in any portion of any indoor facility owned or leased or contracted for by an entity and used routinely or regularly for the provision of health, day care, early childhood development services, education or library services to children under the age of 18, if the services are funded by Federal programs either directly or through State or local governments, by Federal grant, contract, loan, or loan guarantee. The law also applies to children's services that are provided in indoor facilities that are constructed, operated, or

maintained with such federal funds. The law does not apply to children's services provided in private residences; portions of facilities used for inpatient drug or alcohol treatment; service providers whose sole source of applicable federal funds is Medicare or Medicaid; or facilities where WIC coupons are redeemed. Failure to comply with the provisions of the law may result in the imposition of a civil monetary penalty of up to \$1,000 for each violation and/or the imposition of an administrative compliance order on the responsible entity.

By submission of its signed offer, the offeror/contractor (for acquisitions) or applicant/grantee (for grants) certifies that the submitting organization will comply with the requirements of the Act and will not allow smoking within any portion of any indoor facility used for the provision of services for children as defined by the Act.

The submitting organization agrees that it will require that the language of this certification be included in any subawards which contain provisions for children's services and that all subrecipients shall certify accordingly.

6. CERTIFICATION OF INSTITUTIONAL POLICY ON FINANCIAL CONFLICTS OF INTEREST

Note: This certification is applicable to all Research and Development (R&D) Contracts except Phase I SBIR/STTR and Contracts with Federal Agencies.

By Submission of its signed offer, the offeror certifies that:

- (1) there is in effect at the Institution (the term Institution includes any contractor, public or private, excluding a Federal agency) an up-to-date, written and enforced administrative process to identify and manage, financial conflicts of interest with respect to all research projects for which funding is sought or received from the NIH;
- (2) the Institution shall promote and enforce Investigator compliance with this part's requirements including those pertaining to disclosure of significant financial interests;
- (3) the Institution shall manage financial conflicts of interest and provide initial and ongoing FCOI reports to NIH consistent with this part;
- (4) the Institution agrees to make information available, promptly upon request, to the Contracting Officer relating to any Investigator disclosure of financial interests and the Institution's review of, and response to, such disclosure, whether or not the disclosure resulted in the Institution's determination of a financial conflict of interest; and
- (5) the Institution shall fully comply with the requirements of 45 CFR Part 94.

7. DISASTER OR EMERGENCY AREA REPRESENTATION, (Aug 2006), FAR Provision 52.226-3

Note: This provision is applicable for acquisitions that are set-aside for a Disaster or Emergency Area under FAR Subpart 26.2. See Section L.1. of the Solicitation, paragraph entitled "Notice of Disaster or Emergency Area Set-Aside."

- a. *Set-aside area.* The area covered in this contract is: _
[Contracting Officer to fill in with definite geographic boundaries.]

b. *Representations.* The offeror represents as part of its offer that it is, is not a firm residing or primarily doing business in the designated area.

c. Factors to be considered in determining whether a firm resides or primarily does business in the designated area include—

- (1) Location(s) of the firm's permanent office(s) and date any office in the designated area(s) was established;
- (2) Existing state licenses;
- (3) Record of past work in the designated area(s) (e.g., how much and for how long);
- (4) Number of permanent employees the firm employs in the designated area;
- (5) Membership in local and state organizations in the designated area; and
- (6) Other evidence that establishes the firm resides or primarily does business in the designated area.

(e) If the offeror represents it is a firm residing or primarily doing business in the designated area, the offeror shall furnish documentation to support its representation if requested by the Contracting Officer. The solicitation may require the offeror to submit with its offer documentation to support the representation.

(End of Provision)

8. ALTERNATE - REPRESENTATION BY CORPORATIONS REGARDING AN UNPAID DELINQUENT TAX LIABILITY OR A FELONY CONVICTION UNDER ANY FEDERAL LAW

The Consolidated and Further Appropriations Act, 2015 Pub. L 113-235, Division E, Sections 744 and 745 prohibit covered agencies from using funds to enter into contracts with corporations with unpaid federal tax delinquencies or certain felony convictions unless certain conditions are met.

(a) The Offeror represents that —

- (1) It is is not a corporation that was convicted of a felony criminal violation under a Federal or State law within the preceding 24 months.
- (2) It is is not a corporation that has any unpaid Federal tax liability that has been assessed, for which all judicial and administrative remedies have been exhausted or have lapsed, and that is not being paid in a timely manner pursuant to an agreement with the authority responsible for collecting the tax liability.

(End of provision)

**TECHNICAL PROPOSAL COST INFORMATION/SUMMARY OF LABOR
AND DIRECT COSTS**

DIRECT LABOR: Labor Category (Hours)	Year 1 (Hours)	Year 2 (Hours)	Year 3 (Hours)	Year 4 (Hours)	Year 5 (Hours)	Year 6 (Hours)	Year 7 (Hours)	Total
<i>(Title and Name - use additional pages as necessary)</i>								
						N/A	N/A	
Total Hours								
DIRECT LABOR COST:								
	\$	\$	\$	\$	\$	\$	\$	\$
MATERIAL COST:								
	\$	\$	\$	\$	\$	\$	\$	\$
TRAVEL COST:								
	\$	\$	\$	\$	\$	\$	\$	\$
OTHER (Specify):								
	\$	\$	\$	\$	\$	\$	\$	\$
	\$	\$	\$	\$	\$	\$	\$	\$
	\$	\$	\$	\$	\$	\$	\$	\$
	\$	\$	\$	\$	\$	\$	\$	\$
TOTAL DIRECT COST:								

Specific Instructions:

1. Do not include any individual salary information
2. Do not include any indirect cost or fee.
3. Do not submit the total amount of proposal.
4. Submit this information as a portion of the Technical Proposal.

SUMMARY OF RELATED ACTIVITIES

The following specific information must be provided by the offeror pertaining to the Project Director, Principal Investigator, and each of any other proposed key professional individuals designated for performance under any resulting contract.

- a. Identify the total amount of all presently active federal contracts/cooperative agreements/grants and commercial agreements citing the committed levels of effort for those projects for each of the key individuals* in this proposal.

Professional's Name and Title/Position:

Identifying Number	Agency	Total Effort Committed

*If an individual has no obligation(s), so state.

- b. Provide the total number of outstanding proposals, exclusive of the instant proposal, having been submitted by your organization, not presently accepted but in an anticipatory stage, which will commit levels of effort by the proposed professional individuals*.

Professional's Name and Title/Position:

Identifying Number	Agency	Total Effort Committed

*If no commitment of effort is intended, so state.

- c. Provide a statement of the level of effort to be dedicated to any resultant contract awarded to your organization for those individuals designated and cited in this proposal.

Name	Title/Position	Total Proposed Effort

Worksheet for the Vertebrate Animals Section (VAS) under Contract Proposals

This is a worksheet to assist offerors in preparing the VAS as a part of the Technical Proposal for submission to NIH, and to assist reviewers in evaluating the VAS of contract proposals. It provides an overview of the requirements, offeror and reviewer responsibilities, a checklist, and detailed instructions.

Applicability

A VAS is required if the work proposed in a contract proposal involves live vertebrate animals, including animals obtained or euthanized for tissue harvest and generation of custom antibodies.

The criteria in the VAS must be addressed for work proposed at every performance site – this is the site (institution) where procedures with animals will be performed. If the offeror's institution is not the site where animal work will be performed or if the work will be performed at several sites, these performance sites must be identified.

Requirements

If live vertebrate animals are to be used, federal policy requires applicants to address the following criteria:

1. **Description of Procedures.** Provide a concise description of the proposed procedures to be used that involve vertebrate animals in the work outlined in the Request for Proposal (RFP) Statement of Work. Identify the species, strains, ages, sex and total number of animals by species to be used in the proposed work. If dogs or cats are proposed, provide the source of the animals.
2. **Justifications.** Provide justification that the species are appropriate for the proposed research. Explain why the research goals cannot be accomplished using an alternative model (e.g., computational, human, invertebrate, in vitro).
3. **Minimization of Pain and Distress.** Describe the interventions including analgesia, anesthesia, sedation, palliative care and humane endpoints to minimize discomfort, distress, pain and injury.
4. **Euthanasia.** State whether the method of euthanasia is consistent with the recommendations of the American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals. If not, describe the method and provide a scientific justification.

Offeror Responsibilities

Each of the first three criteria must be addressed, and the fourth if applicable, in the VAS portion of the Technical Proposal of NIH RFP. All of the items must be addressed and evaluated by reviewers as appropriate for an application to be rated as ACCEPTABLE. The VAS portion must be considered as ACCEPTABLE prior to award.

Reviewer Responsibilities

Members of scientific review groups (SRGs) must evaluate the VAS to determine if plans for the use of vertebrate animals are appropriate and acceptable relative to the scientific work proposed. Reviewers will assess the VAS for proposals proposing the use of chimpanzees as they would any other proposal.

NIH Staff Responsibilities

- **Project Officer**
 - a) Assists the contracting officer in determining the acceptability of the revised VAS.

- **Contracting Officer**

- a) Provides reviewers with instructions for reviewing the VAS (e.g., worksheet), noting that all criteria must be evaluated as appropriate for the VAS to be ACCEPTABLE.
- b) Subsequent to SRG review, determines the competitive range, as applicable, and if discussions are held, provides the offeror with the opportunity to address the concerns raised by the reviewers.
- c) With the advice of the project officer and OLAW, as necessary, determines if the concerns have been resolved and the VAS can be considered ACCEPTABLE.
- d) Confirms whether the offeror has an OLAW-approved Assurance and IACUC approval.
- e) Makes contract awards.

Checklist

Performance sites:

- If the applicant's institution is not where animal work will be performed, are all collaborative performance sites identified?
- If more than one performance site is planned, are descriptions of animal use addressing the required criteria provided for each site?

1. Describe the animals and their proposed use. Address the following for all species to be used:

- Species
- Strains
- Ages
- Sex
- Total number of animals by species to be used
- Concise, complete description of proposed procedures (i.e., sufficient information for evaluation)
- Source, only if dogs or cats are proposed

2. Provide justifications for:

- Choice of species
- Why research goals cannot be accomplished using an alternative model (e.g., computational, human, invertebrate, in vitro)

3. Describe interventions to minimize discomfort, distress, pain and injury. Examples of the kinds of items that may be appropriate to include are:

- Circumstances relevant to the proposed work, when animals may experience discomfort, distress, pain or injury
- Procedures to alleviate discomfort, distress, pain or injury
- Identify (by name or class) any tranquilizers, analgesics, anesthetics and other treatments (e.g., antibiotics) and describe their use
- Provisions for palliative care or housing that may be necessary after experimental procedures
- Plans for post-surgical care, if survival surgeries are proposed
- Indicators for humane experimental endpoints, if relevant

4. State if method of euthanasia is consistent with AVMA Guidelines. If method does not follow the guidelines:

- Describe the method of euthanasia
- Provide a scientific justification

Instructions

Typically, all of the required elements for the VAS can be addressed within 1-2 pages. The SRG will evaluate information provided in the VAS according to the technical evaluation criteria specified in Section M of the RFP. During discussions, the contracting officer will provide any concerns expressed during the review by the SRG and provide the offeror an opportunity to respond to the concerns. After award, the contract will be coded in the Departmental Contracts Information System (DCIS) as a contract where animals will be used. Offerors should be aware that NIH may release information contained in contract awards pursuant to a Freedom of Information Act request or pursuant to a protest, either before or after award.

1. Description of Procedures

Offerors must include a concise, complete description of the proposed procedures. The description must include sufficient detail to allow evaluation of the procedures.

Examples of the types of procedures that may be described include:

- blood collection
- surgical procedures
- administration of substances
- tumor induction
- post-irradiation procedures

In describing the animals, offerors must provide the following information:

- Species
- Strain
- Ages
- Sex
- Total number of animals to be used by species
- Source of the animals, if dogs or cats are proposed

2. Justifications

Offerors must justify the use of animals in the proposed research. U.S. Government Principles require contractors to consider mathematical models, computer simulation, and in vitro biological systems. The justification should indicate why the research goals cannot be accomplished using an alternative model (e.g., computational, human, invertebrate, in vitro). Rationale for the choice of species must be provided (e.g., advantages of the species chosen and why alternative species are not appropriate). Discuss why less highly evolved or simpler animal models are not appropriate. For example, the use of non-human primates, dogs or cats should be thoroughly justified.

3. Minimize of Pain and Distress

Offerors should identify procedures or circumstances that may result in more than momentary discomfort, distress, pain or injury. Interventions to alleviate discomfort, distress or pain should be described. If pharmacological agents are used, the agents may be specified by name or class. Any additional (e.g., non-pharmaceutical) means to avoid discomfort, distress, pain or injury may be briefly described, including palliative care. The manner, circumstances and duration of all post-surgical provisions and care may be described. If special housing is necessary following surgery or manipulations, the VAS may describe these. If procedures (e.g., pharmacological, surgical) might lead to severe discomfort, distress, pain or injury, indicators for humane endpoints and euthanasia (e.g., severe infection, respiratory distress, failure to eat, tumor size) may be described. All of these issues are particularly important for survival surgeries. If multiple surgeries are proposed, these should be well justified and provisions to avoid any potential complications may be described.

4. Euthanasia

Investigators should state whether euthanasia will be performed and indicate if the method of euthanasia is

consistent with AVMA guidelines. If consistent, no further information is needed. If it isn't consistent, they must describe the method of euthanasia and provide scientific justification.

Resources

- [Grant Application VAS Worksheet \(PDF\)](#) – an optional tool for grant application review
- [Contract Proposal VAS Worksheet \(PDF\)](#) – an optional tool for contract proposal review
- [VAS Factsheet \(PDF\)](#)
- [What Investigators Need to Know About the Use of Animals \(PDF\)](#) – *ILAR Journal* 2014; 54(3):324-328.

References

The guidance in this worksheet is based on Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy) and federal requirements. The PHS Policy incorporates the standards in the *Guide for the Care and Use of Laboratory Animals* and the *U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training*, and requires that euthanasia be conducted according to the *AVMA Guidelines for the Euthanasia of Animals*. Additional background information and references are available on the OLAW website (<http://olaw.nih.gov>).

- PHS Policy
<http://grants.nih.gov/grants/olaw/references/phspol.htm>
- U.S. Government Principles
<http://grants.nih.gov/grants/olaw/references/phspol.htm#USGovPrinciples>
- Guide for the Care and Use of Laboratory Animals
http://www.nap.edu/catalog.php?record_id=12910
- AVMA Guidelines for the Euthanasia of Animals
<https://www.avma.org/KB/Policies/Documents/euthanasia.pdf>
- NIH Guide for Grants and Contracts Notice - NOT-OD-10-027
<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-027.html>

Additional Technical Proposal Instructions

A detailed proposal must be submitted indicating how each aspect of the Statement of Work (SOW) is to be accomplished. Your narrative must be in as much detail as you consider necessary to fully explain your proposed technical approach or methods. The technical proposal must reflect a clear understanding of the nature of the work being undertaken. The technical proposal must also include information on how the project is to be organized, staffed, and managed. Information must be provided which will demonstrate your understanding and management of tasks related to bioanalytical methods utilization, pharmacokinetic evaluations and data analysis.

1. Technical Discussions

The technical discussions included in the technical proposal must respond to the items set forth below:

A. Personnel

OFFERORS MUST ASSURE THAT THE PROJECT DIRECTOR/PROJECT MANAGER AND ALL OTHER PERSONNEL PROPOSED ARE NOT COMMITTED ON FEDERAL GRANTS AND CONTRACTS FOR MORE THAN A TOTAL OF 100 PERCENT OF THEIR TIME. IF THE SITUATION ARISES WHERE IT IS DETERMINED THAT A PROPOSED EMPLOYEE IS COMMITTED FOR MORE THAN 100 PERCENT OF HIS OR HER TIME, THE GOVERNMENT WILL REQUIRE ACTION ON THE PART OF THE OFFEROR TO CORRECT THE TIME COMMITMENT.

(1) Project Manager

A Project Director/Project Manager responsible for overseeing the project must be named. This individual must demonstrate leadership experience in pharmacologic and pharmacokinetic investigation of therapeutic agents (particularly antitumor agents) and have demonstrated an ability to lead a multi-disciplinary team of scientists, which must include individuals with analytical methods and pharmacokinetic expertise. He or she must have attained doctorate level (or equivalent) educational status in pharmacology, pharmaceutical sciences, or a closely related discipline. A resume for the proposed Project Director/Project Manager must demonstrate his/her education, background, recent experience, and specific scientific accomplishments. A complete bibliographic listing of published or accepted papers as well as any unpublished technical study reports must also be provided (proprietary compound names may be censored). Study reports that have been submitted to the FDA as part of an IND or NDA is considered of equal importance with peer-reviewed publications in demonstrating experience.

(2) Other Professional Personnel

All other professional personnel must be named, indicating their present responsibilities and availabilities to the project. Current resumes of all proposed personnel, which indicate education, scientific background, recent experience,

and specific scientific or technical accomplishments, must be provided. Unrelated information or resumes of individuals not assigned to, or involved with, the proposed project are neither necessary nor desired, and will be considered as detracting from the proposal. A bibliography listing publications (including any study reports) relevant to this project must be included for each individual proposed.

Particular emphasis must be placed on the senior professional staff who will oversee and manage the specific technical tasks described in the SOW [e.g., bioanalytical mass spectrometry, animal dosing and sample collection, pharmacokinetic data analyses, metabolite identification, drug metabolism, etc.].

Experience with one or more of the following techniques is considered desirable, but will not be an absolute requirement for award: (1) the ability to perform pharmacokinetic evaluations in large animals such as dogs and non-human primates; (2) expertise with specialized animal procedures (e.g., bile duct cannulation, surgical techniques to perform site specific absorption or hepatic clearance evaluations.); (3) the identification and quantitation of biological therapeutic agents (e.g., immunotoxins, antibodies, oligonucleotides) using techniques such as ELISA, PCR, immunoblots, and mass spectroscopy

(3) Additional Personnel

List names, titles, level of effort, and proposed duties of any additional personnel, including technical and support staff, proposed on the contract. Current resumes of the proposed personnel, which indicate education, training, and recent experience and accomplishments relevant to their proposed activities, must be provided.

Since technical expertise will be an important consideration in the work to be performed, particular emphasis must be placed on the overall technical capabilities of the group, identifying those individuals who will be responsible for specific technical tasks, (e.g., bioanalytical mass spectrometry, animal dosing and sample collection, pharmacokinetic data analyses, metabolite identification, etc.).

(4) Subcontractors and Consultants

List names, titles, level of effort, and proposed duties of any personnel who are proposed on a subcontract or consultant basis. The technical areas, character, and extent of subcontract or consultant activity must be indicated and the anticipated sources must be specified and described. 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 or Curriculum Vitae (CV) for each proposed subcontractor employee or consultant must be provided, but this does not meet the requirement for evidence of availability. Commitment letters for use of consultants must include:

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

- How rights to publications and patents will be handled.

B. Technical Approach and Awareness of the Problem

Describe in detail how the group will be organized, both scientifically and administratively. The proposal must include a detailed description of at least one recent example from the group's own experience with the implementation of a method for the analysis of a drug in biological fluids such as plasma or urine. Also include a description of a pharmacokinetic study in the mouse, rat, dog or other species recently performed by the proposed group of personnel and the approach used to model the data. Discuss in detail previous work experiences and approaches that will be used in conducting the proposed pharmacological evaluations, encompassing the items listed in the SOW. This discussion must detail the breadth of experience of the proposed project team with analyses of diverse chemical structures and the conduct of *in vivo* and *in vitro* pharmacokinetic evaluations.

Additional discussions must show your awareness and use of analytical method standard operating procedures (SOPs) suitable for early discovery-stage evaluations as well as approaches to be used for later-stage non-clinical and clinical samples; available techniques for collecting single or multiple blood samples from individual rodents; the ability to conduct pharmacokinetic-pharmacodynamic-efficacy evaluations in tumor-bearing animals, and the procedures to be used for small animal necropsy, including collection, processing, analysis, shipping, and storage of selected tissue samples.

Successful contractors are expected to apply state-of-the-art instrumental analysis techniques to the implementation and validation of quantitative assays for test compounds in plasma, tissues, and/or other biological fluids. The core technique required is liquid chromatography tandem mass spectrometry (LC-MS/MS). Additional desirable techniques may include (but are not limited to) gas chromatography, capillary electrophoresis, and immunoassays.

The ability to receive, process, analyze, and properly dispose of specimens (plasma, urine, tumor) from human clinical trials is highly desirable. Evidence of Institutional Review Board oversight must be provided.

Discuss in detail the procedures for carrying out the work indicated in each of the sample Task Orders/protocols provided in Appendix A. Where applicable, discuss suitable analytical methods implementation, numbers of animals for study, implanting and staging xenograft experiments, procedures for collection of blood or tissue samples, criteria for moribund sacrifice, and data collection and analysis.

C. Facilities and Equipment

The work to be conducted will NOT require compliance with FDA Good Laboratory Practice (GLP) regulations.

Describe in detail the laboratory space and equipment available for the performance of the work proposed. A floor plan to scale, indicating relevant dimensions must be provided for all laboratory space available to this project, identifying the areas where

different facets of the work are conducted. In situations where more than one building or institution is involved, a clear description must be given of the locations of all sites, the distances and travel time between them, and (if proposed) the procedures for transport of animals and/or biological samples from one site to the other.

A complete description of animal facilities to be used on the project must be provided, along with relevant floor plans to scale. Accreditation of the facility by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC International) is highly desirable. A copy of the latest review, if applicable, must be included. Offerors must have appropriate facilities and equipment to perform pharmacokinetic evaluations in rodents (and optionally in larger species) using various routes of administration (e.g., intravenous, oral, subcutaneous, and intraperitoneal injections and/or infusions).

A description of all major equipment available for the work must be provided and its location noted. Particular attention must be given to the analytical instrumentation available for this project. The availability and capacity of mass spectrometric instrumentation in conjunction with liquid chromatography for routine quantitative analysis of samples from pharmacokinetic evaluations must be stated. If this equipment is NOT under the direct control of the Project Manager, procedures for assuring suitable access for this project must be described and documented. Availability of appropriate mass spectrometric instrumentation for elucidation of chemical structures is also required.

Information must be provided on institutional procedures for equipment maintenance, calibration, and validation. When equipment is only available on a shared basis, some evidence must be provided as to who is responsible for controlling access and how the determination of priority of usage will be made (letter of commitment from Department Head, etc).

A description of computer hardware and software available for the project must be provided. Particular emphasis must be given to the pharmacokinetic modeling software to be used. A description of available electronic information and/or library resources must be provided; if not completely in-house, a description must be given of outside facilities within easy traveling distance of the institution that are available for use.

D. Organizational Experience and Support

Organizational experience is defined as the past accomplishment of work which is comparable or related to the effort required by this RFP. This includes overall offeror or corporate experience, not necessarily the experience and/or past performance of individuals who are offered as personnel in your proposal.

The established existence of an organizational environment that fosters pharmacological investigations of therapeutic agents must be demonstrated, especially for the recent past. Examples of institutional accomplishments in these areas must be provided. An organizational chart(s) that shows lines of authority within the organization and the project team must be included. Assurance must be provided that the organization is capable and willing to provide appropriate

personnel and resources to accomplish the stated work over the period of performance of any contract awarded.

E. Safety and Security

Each test agent will be considered potentially hazardous. Therefore, all necessary precautions must be taken to protect personnel and the environment against possible exposure to the agents being tested. The Contractor must perform all work associated with this contract in accordance with all applicable Federal, State and local regulations for Occupational exposure to hazardous chemicals in laboratories. (e.g. 29 CFR 1910.1450) and follow regulations governing transportation and disposal of hazardous waste.

Describe fully the proposing organization's policy on safety and security. Describe laboratory safety controls and procedures for handling and disposing of carcinogens and toxic waste materials proposed to be used for this project. Describe procedures for the prevention of contamination during laboratory operations. Indicate your awareness of OSHA regulations, etc., and provide documentation of any recent OSHA inspections and compliance. Please supply one copy of the organization's current Health and Safety Manual. Describe current security procedures for protection of animal and other facilities.

F. Additional Technical Proposal Information

- (1) In assessing proposals relative to the proper care and use of laboratory animals, guidance from the following references will be utilized:
 - a. *Guide for the Care and Use of Laboratory Animals 8th ed.*, National Research Council, 2011
<http://www.ncbi.nlm.nih.gov/books/NBK54050/>
 - b. Public Health Service Policy on Humane Care and Use of Laboratory Animal@ revised 2015.
<https://grants.nih.gov/grants/olaw/references/phspol.htm>.
- (2) Proposals that 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 accomplishing the project objectives.
- (3) Separate technical and cost/business evaluations will be performed. Inter-relationships of the two will be assessed consistent with DHHS regulations concerning the consideration of cost and other factors in making awards.
- (4). The technical evaluation is conducted in accordance with the weighted technical evaluation criteria by an initial review panel. This evaluation produces a numerical score that is based solely upon the information in the offeror's proposal.

H. OTHER CONSIDERATIONS

- (1) Data provided to the Contractor under this contract must be treated confidentially. For example, the data to be treated confidentially is associated with certain *Adiscreet* compounds that are not available to the public. When compounds are assigned to the Contractor, these *discreet* compounds will be identified by the letter "D" as a prefix to the compound's NSC number. Under no circumstances are chemicals or drugs or any information associated with these chemicals or drugs to be released or divulged without prior written approval of the NCI Project Officer.
- (2) The Government requires that all data generated under the projected contracts be immediately available for its review and provisions be made to maintain confidentiality of all data. Authority to release data may be granted only by the Contracting Officer together with the Project Officer and must be in writing.
- (3) Record and discuss specific factors not included elsewhere which support your proposal. Using specifically titled subparagraphs, items may include:
 - a. Unique arrangements, equipment, *etc.*, which none or very few organizations are likely to have which are advantageous for effective implementation of this program.
 - b. Equipment and unusual operating procedures established to protect personnel from hazards associated with this project.

APPENDIX A

The following sample Task Order Requests are appended to this solicitation:

- (1) Pharmacokinetic and Bioavailability Evaluations of Anticancer Compounds in Mice
- (2) Pharmacokinetic-Pharmacodynamic-Efficacy Evaluation of Anticancer Compounds in Tumor-Bearing Mice.
- (3) Analytical Support for Pharmacology Evaluations with Selected Anticancer Agents
- (4) Determination of [NSC – *to be determined*] in Plasma and Urine Samples from an NCI-supported Human Phase I Clinical Trial.
- (5) Kick-off Meeting with NCI Staff

Technical and business responses must be provided in your proposal, according to the specific instructions included in each sample. Note that Task Orders 1-4 are for informational and evaluation purposes only – no actual awards will be made. For Task Order 5, it is anticipated that a Task for participation in a kick-off meeting with the NCI will be made at the time of award of all contracts resulting from this solicitation.

Provision of the Social Security Number is voluntary. Social Security Numbers are requested for the purpose of accurate and efficient identification, review, and management of NIH Extramural Programs. Authority for requesting this information is provided by Title III, Section 301, and Title IV of the Public Health Service Act, as amended.



U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Washington, D.C. 20201

**OFFICE OF SMALL AND DISADVANTAGED BUSINESS UTILIZATION
SMALL BUSINESS SUBCONTRACTING PLAN**

*The following outline meets the minimum requirements of section 8(d) of the Small Business Act, as amended, and implemented by the Federal Acquisition Regulations (FAR) Subpart 19.7. The U.S. Department of Health and Human Services (HHS), Office of Small and Disadvantaged Business Utilization (OSDBU) recommend offerors use the following format to submit proposed Individual Subcontracting Plans, including modifications. It is not intended to replace any existing Corporate/Commercial Plan that is more extensive. A subcontracting Plan is required if the estimated cost of the contract **may exceed \$650,000 (\$1,500,000 for construction)** Small businesses are excluded. Questions should be forwarded to the Contracting Officer or Operating Division (OPDIV) Small Business Specialist.*

HHS Operating Division (OPDIV): _____

SOLICITATION OR CONTRACT NUMBER: _____

DATE OF PLAN: _____

CONTRACTOR: _____

ADDRESS: _____

STATE/ZIP CODE _____

DUNN & BRADSTREET NUMBER: _____

ITEM/SERVICE (Description): _____

NEW/INITIAL CONTRACT

PERIOD OF CONTRACT PERFORMANCE (MM/DD/YYYY - MM/DD/YYYY): _____

Base (if options apply) \$ _____ Performance Period/Quantity _____

Option 1: \$ _____ Performance Period/Quantity _____

Option 2: \$ _____ Performance Period/Quantity _____

Option 3: \$ _____ Performance Period/Quantity _____

Option 4: \$ _____ Performance Period/Quantity _____

\$ _____ Total Contract Cost

CONTRACT MODIFICATION (if applicable)

NEW PERIOD OF CONTRACT PERFORMANCE (MM/DD/YYYY - MM/DD/YYYY): _____

Original/Base \$ _____ Performance Period/Quantity _____

Modification \$ _____ Performance Period/Quantity _____

Task Order \$ _____ Performance Period/Quantity _____

\$ _____ Modified Total Contract Cost

Failure to include the essential information of FAR Subpart 19.7 may be cause for either a delay in acceptance or the rejection of a bid or offer when a subcontracting plan is required. "SUBCONTRACT," as used in this clause, means any agreement (other than one involving an employer-employee relationship) entered into by a Federal Government prime contractor or subcontractor requesting supplies or services required for performance of the contract or subcontract.

If assistance is needed to locate small business sources, contact the Small Business Specialist (SBS) supporting the OPDIV. SBS contact information is located on the OSDBU website (<http://www.hhs.gov/about/smallbusiness/osdbustaff.html>) or you may contact the OSDBU headquarters at (202) 690-7300.

HHS current subcontracting goal is **33.0%** for Small Business (hereafter referred to as SB), **5.00%** for Small Disadvantaged Business, including 8(a) Program Participants, Alaska Native Corporations (ANC) and Indian Tribes (hereafter referred to as SDB), **5.00%** for Women-Owned Small Business and Economically Disadvantaged Women-Owned Small Business (hereafter referred to as WOSB), **3.00%** HubZone business (hereafter referred to as HUBZone), 3.00% Veteran Owned Small Business (hereafter referred to as VOSB) and **3.00%** Service Disabled Veteran-Owned Small Business (hereafter referred to as SDVOSB) concerns for **Fiscal Year (FY) 2012**. For this procurement, HHS expects all proposed subcontracting plans to contain at a minimum the aforementioned percentages.

These percentages shall be expressed as percentages of the total estimated subcontracting dollars.

1. Type of Plan (check one)

_____ **Individual plan** (all elements developed specifically for this contract and applicable for the full term of this contract).

_____ **Master plan** (goals developed for this contract) all other elements standardized and approved by a lead agency Federal Official; must be renewed every three years and contractor must provide copy of lead agency approval.

_____ **Commercial products/service plan** (goals are negotiated with the initial agency on a company-wide basis rather than for individual contracts) this plan applies to the entire production of commercial service or items or a portion thereof. The contractor sells commercial products and services customarily used for non-government purposes. The plan is effective during the offeror's fiscal year (attach a copy). **The Summary Subcontracting Report (SSR) must include a breakout of subcontracting prorated for HHS and other Federal agencies.**

2. Goals

Below indicate the dollar and percentage goals for Small Business (SB), Small Disadvantaged (SDB) including Alaska Native Corporations and Indian Tribes, Women-owned and Economically Disadvantaged Women-Owned (WOSB), Historically Underutilized Business Zone (HUBZone), Veteran Owned Small Business (VOSB), Service-Disabled Veteran-Owned (SDVOSB) Small Businesses and "Other than Small Business" (Other) as subcontractors. Indicate the base year and each option year, as specified in FAR 19.704 or project annual subcontracting base and goals under commercial plans. If any contract has more four options, please attach additional sheets which illustrate dollar amounts and percentages. **PLEASE NOTE: Zero dollars is not an acceptable goal for the SB, SDB, WOSB, HUBZone, VOSB or SDVOSB categories since this does not demonstrate a good faith effort throughout the period of performance of the contract.** Formula for below: 2.b. + 2.h. = 2.a.

a. **Total estimated dollar value of ALL planned subcontracting**, i.e., with ALL types of concerns under this contract is _____ (Base Period - if options apply).

FY ___1st Option FY ___2nd Option FY ___3rd Option FY ___4th Option
\$ _____ \$ _____ \$ _____ \$ _____

b. **Total estimated dollar value and percent of planned subcontracting with SMALL BUSINESSES** (including SDB, WOSB, HUBZone, VOSB and SDVOSB): (% of "a")

\$ _____ and _____% (Base Period - if options apply)
FY ___1st Option FY ___2nd Option FY ___3rd Option FY ___4th Option
\$ _____ \$ _____ \$ _____ \$ _____

c. Total estimated dollar value and percent of planned subcontracting with **SMALL DISADVANTAGED BUSINESSES**: (% of "a") \$ _____ and _____% (Base Period - if options apply)

FY ___1st Option FY ___2nd Option FY ___3rd Option FY ___4th Option
\$ _____ \$ _____ \$ _____ \$ _____

d. Total estimated dollar value and percent of planned subcontracting with **WOMEN-OWNED SMALL BUSINESSES**: (% of "a") \$ _____ and _____% (Base Period - if options apply)

FY ___1st Option FY ___2nd Option FY ___3rd Option FY ___4th Option
\$ _____ \$ _____ \$ _____ \$ _____

e. Total estimated dollar and percent of planned subcontracting with **HUBZone SMALL BUSINESSES**: (% of "a") \$ _____ and _____% (Base Period - if options apply)

FY ___1st Option FY ___2nd Option FY ___3rd Option FY ___4th Option
\$ _____ \$ _____ \$ _____ \$ _____

f. Total estimated dollar and percent of planned subcontracting with **VETERAN-OWNED SMALL BUSINESSES**: (% of "a") \$ _____ and _____% (Base Period - if options apply)

FY ___1st Option FY ___2nd Option FY ___3rd Option FY ___4th Option
\$ _____ \$ _____ \$ _____ \$ _____

g. Total estimated dollar and percent of planned subcontracting with **SERVICE-DISABLED VETERAN-OWNED SMALL BUSINESSES**: (% of "a") \$ _____ and _____% (Base Period - if options apply)

FY ___1st Option FY ___2nd Option FY ___3rd Option FY ___4th Option
\$ _____ \$ _____ \$ _____ \$ _____

h. Total estimated dollar and percent of planned subcontracting with **"OTHER THAN SMALL BUSINESSES"** (As defined by the Small Business Administration as "any entity that is not classified as a small business. This includes large businesses, state and local governments, non-profit organizations, public utilities, educational institutions and foreign-owned firms.) (% of "a") \$ _____ and _____% (Base Period - if options apply)

FY ___1st Option FY ___2nd Option FY ___3rd Option FY ___4th Option
\$ _____ \$ _____ \$ _____ \$ _____

- i. Provide a description of ALL the products and/or services to be subcontracted under this contract, and indicate the size and type of business supplying them (check all that apply):

Products and/or Services	Other	Small Business	SDB	WOSB	Hubz	VOSB	SDVOSB
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							

- j. Provide a description of the method used to develop the subcontracting goals for SB, SDB, WOSB, HUBZone and SDVOSB concerns. Address efforts made to ensure that maximum practicable subcontracting opportunities have been made available for those concerns and explain the method used to identify potential sources for solicitation purposes. Explain the method and state the quantitative basis (in dollars) used to establish the percentage goals. Also, explain how the areas to be subcontracted to SB, WOSB, HUBZone, VOSB and SDVOSB concerns were determined, how the capabilities of these concerns were considered contract opportunities and how such data comports with the cost proposal. Identify any source lists or other resources used in the determination process. (Attach additional sheets, if necessary.)
-
-

- k. Indirect costs have ____ have not ____ been included in the dollar and percentage subcontracting goals above (check one).

- I. If indirect costs have been included, explain the method used to determine the proportionate share of such costs to be allocated as subcontracts to SB, SDB, WOSB, HUBZone, VOSB and SDVOSB concerns:

3. Program Administrator:

NAME: _____

TITLE: _____

ADDRESS: _____

TELEPHONE: _____

E-MAIL: _____

Duties: Does the individual named above have general overall responsibility for the company's subcontracting program, i.e., developing, preparing, and executing subcontracting plans and monitoring performance relative to the requirements of those subcontracting plans and perform the following duties? (If NO is checked, please who in the company performs those duties, or indicate why the duties are not performed in your company on a separate sheet of paper and submit with the proposed subcontracting plan.)

- a. Developing and promoting company-wide policy initiatives that demonstrate the company's support for awarding contracts and subcontracts to SB, SDB, WOSB, HUBZone, VOSB and SDVOSB concerns; and for assuring that these concerns are included on the source lists for solicitations for products and services they are capable of providing; yes no
- b. Developing and maintaining bidder source lists of SB, SDB, WOSB, HUBZone, VOSB and SDVOSB concerns from all possible sources; yes no
- c. Ensuring periodic rotation of potential subcontractors on bidder's lists; yes no
- d. Assuring that SB, SDB, WOSB, HUBZone, VOSB and SDVOSB businesses are included on the bidders' list for every subcontract solicitation for products and services that they are capable of providing. yes no

- e. Ensuring that Requests for Proposals (RFPs) are designed to permit the maximum practicable participation of SB, SDB, WOSB, HUBZone, VOSB and SDVOSB concerns. yes no
- f. Reviewing subcontract solicitations to remove statements, clauses, etc., which might tend to restrict or prohibit small, 8(a), SDB, WOSB, HUBZone, VOSB and SDVOSB small business participation. yes no
- g. Accessing various sources for the identification of SB, SDB, WOSB, HUBZone, VOSB and SDVOSB concerns to include the Central Contractor Registration (<http://www.ccr.gov/>), local small business and minority associations, local chambers of commerce and Federal agencies' Small Business Offices; yes no
- h. Establishing and maintaining contract and subcontract award records; yes no
- i. Participating in Business Opportunity Workshops, Minority Business Enterprise Seminars, Trade Fairs, Procurement Conferences, etc; yes no
- j. Ensuring that SB, SDB, WOSB, HUBZone, VOSB and SDVOSB concerns are made aware of subcontracting opportunities and assisting concerns in preparing responsive bids to the company; yes no
- k. Conducting or arranging for the conduct of training for purchasing personnel regarding the intent and impact of Section 8(d) of the Small Business Act, as amended; yes no
- l. Monitoring the company's subcontracting program performance and making any adjustments necessary to achieve the subcontract plan goals; yes no
- m. Preparing and submitting timely, required subcontract reports; yes no
- n. Conducting or arranging training for purchasing personnel regarding the intent and impact of 8(d) of the Small Business Act on purchasing procedures; yes no
- o. Coordinating the company's activities during the conduct of compliance reviews by Federal agencies; and yes no
- p. Other duties: _____

4. Equitable Opportunity

Describe efforts the offeror will undertake to ensure that SB, SDB, WOSB, HUBZone, VOSB and SDVOSB concerns will have an equitable opportunity to compete for subcontracts. These efforts include, but are not limited to, the following activities:

a. Outreach efforts to obtain sources:

1. Contact minority and small business trade associations; 2) contact business development organizations and local chambers of commerce; 3) attend SB, SDB, WOSB, HUBZone, VOSB and SDVOSB procurement conferences and trade fairs; 4) review sources from the Central Contractor Registration (<http://www.ccr.gov/>); 5) review sources from the Small Business Administration (SBA), Central Contractor Registration (CCR); 6) Consider using other sources such as the National Institutes of Health (NIH) e-Portals in Commerce, (e-PIC), (<http://epic.od.nih.gov/>). The NIH e-PIC is not a mandatory source; however, it may be used at the offeror's discretion; and 7) Utilize newspaper and magazine ads to encourage new sources.

b. Internal efforts to guide and encourage purchasing personnel:

1. Conduct workshops, seminars and training programs;
2. Establish, maintain, and utilize SB, SDB, WOSB, HUBZone, VOSB and SDVOSB source lists, guides, and other data for soliciting subcontractors; and
3. Monitor activities to evaluate compliance with the subcontracting plan.

Additional efforts:

5. Flow Down Clause

The contractor agrees to include the provisions under FAR 52.219-8, "Utilization of Small Business Concerns," in all acquisitions exceeding the simplified acquisition threshold that offers further subcontracting opportunities. All subcontractors, except small business concerns, that receive subcontracts in excess of \$650,000 (\$1,500,000 for construction) must adopt and comply with a plan similar to the plan required by FAR 52.219-9, "Small Business Subcontracting Plan." Note: In accordance with FAR 52.212-5(e) and 52.244-6(c) the contractor is not required to include flow-down clause FAR 52.219-9 if it is subcontracting commercial items.

6. Reporting and Cooperation

The contractor gives assurance of 1) cooperation in any studies or surveys that may be required; 2) submission of periodic reports which illustrate compliance with the subcontracting plan; 3) submission of its Individual Subcontracting Report (ISR) and Summary Subcontract Report (SSR); and 4) subcontractors submission of ISRs and SSRs. **ISRs and SSRs shall be submitted via the Electronic Subcontracting Reporting System (eSRS) website <https://esrs.symplicity.com/index?tab=signin&cck=1>**

Reporting Period	Report Due	Due Date
Oct 1 - Mar 31	ISR	4/30
Apr 1 - Sept 30	ISR	10/30
Oct 1 - Sept 30	SSR	10/30
Contract Completion	Year End SDB Report	30 days after completion

Please refer to FAR Part 19.7 for instruction concerning the submission of a Commercial Plan: SSR is due on 10/30 each year for the previous fiscal year ending 9/30.

- a. Submit ISR (bi-annually) for the awarding Contracting Officer's review and acceptance via the eSRS website.
- b. Currently, SSR (annually) must be submitted for the HHS eSRS Agency Coordinator review and acceptance via the eSRS website. (**Note:** Log onto the OSDDBU website to view the HHS Agency Coordinator contact information (<http://www.hhs.gov/about/smallbusiness/osdbustaff.html>)).

Note: The Request for Proposal (RFP) will indicate whether a subcontracting plan is required. Due to the nature and complexity of many HHS contracts, particularly the Centers for Medicare and Medicaid (CMS), the contractor may not be required to submit its subcontracting reports through the eSRS. The Contracting Officer will confirm reporting requirements prior to the issuance of an award. For more information, contact Courtney Carter, Agency Coordinator-eSRS (Courtney.Carter@hhs.gov).

7. Record keeping

FAR 19.704(a) (11) requires a list of the types of records your company will maintain to demonstrate the procedures adopted to comply with the requirements and goals in the subcontracting plan. The following is a recitation of the types of records the contractor will maintain to demonstrate the procedures adopted to comply with the requirements and goals in the subcontracting plan. These records will include, but not be limited to, the following:

- a. SB, SDB, WOSB, HUBZone, VOSB and SDVOSB source lists, guides and other data identifying such vendors;
- b. Organizations contacted in an attempt to locate SB, SDB, WOSB, HUBZone, VOSB and SDVOSB sources;
- c. On a contract-by-contract basis, records on all subcontract solicitations over \$100,000, which indicate for each solicitation (1) whether SB, SDB, WOSB, HUBZone, VOSB and/or SDVOSB concerns were solicited, if not, why not and the reasons solicited concerns did not receive subcontract awards;

- d. Records to support other outreach efforts, e.g., contacts with minority and small business trade associations, attendance at small and minority business procurement conferences and trade fairs;
- e. Records to support internal guidance and encouragement provided to buyers through (1) workshops, seminars, training programs, incentive awards; and (2) monitoring performance to evaluate compliance with the program and requirements; and
- f. On a contract-by-contract basis, records to support subcontract award data including the name, address, and business type and size of each subcontractor. (This is not required on a contract-by-contract basis for commercial plans.)
- g. Other records to support your compliance with the subcontracting plan: (Please describe)

8. Timely Payments to Subcontractors

FAR 19.702 requires your company to establish and use procedures to ensure the timely payment of amounts due pursuant to the terms of your subcontracts with SB concerns, SDB, WOSB, HUBZone, VOSB and SDVOSB concerns.

Your company has established and used such procedures: _____ yes _____ no

9. Description of Good Faith Effort

Maximum practicable utilization of SB, SDB, WOSB, HUBZone, VOSB and SDVOSB concerns as subcontractors in Government contracts is a matter of national interest with both social and economic benefits. **When a contractor fails to make a good faith effort to comply with a subcontracting plan, these objectives are not achieved, and 15 U.S.C. 637(d) (4) (F) directs that liquidated damages shall be paid by the contractor.** In order to demonstrate your compliance with a good faith effort to achieve the SB, SDB, WOSB, HUBZone, VOSB and SDVOSB small business subcontracting goals, outline the steps your company plans to take. These steps will be negotiated with the contracting official prior to approval of the plan.

SIGNATURE PAGE

Signatures Required:

This subcontracting plan was submitted by:

Signature: _____

Typed/Print Name: _____

Title: _____

Date: _____

This plan was reviewed by:

Signature: _____

Typed/Print Name: _____

Title: Contracting Officer Date: _____

This plan was reviewed by:

Signature: _____

Typed/Print Name: _____

Title: HHS Small Business Specialist Date: _____

This plan was reviewed by:

Signature: _____

Typed/Print Name: _____

Title: Small Business Administration Procurement Center Representative

Date: _____

This plan was approved by:

Signature: _____

Typed/Print Name: _____

Title: Contracting Officer Date: _____

Skip Navigation

BREAKDOWN OF PROPOSED ESTIMATED COST (PLUS FEE) AND LABOR HOURS

INSTRUCTIONS FOR USE OF THE FORMAT

1. Refer to Business Proposal Instructions, Section L of this solicitation. The Instructions contain the requirements for proper submission of cost/price data which must be adhered to.

2. This format has been prepared as a universal guideline for all solicitations issued by the National Cancer Institute. It may require amending to meet the specific requirements of this solicitation. For example, this solicitation may require the submission of cost/price data for three years listed on this form. (See Section L.1., General Information for the estimated duration of this project.) If this solicitation is phased, identify each phase in addition to each year. Total each year, phase, and sub-element.

3. This format must be used to submit the breakdown of all proposed estimated cost elements. List each cost element and sub-element for direct costs, indirect costs and fee, if applicable. In addition, provide detailed calculations for all items. For example:

a. For all personnel, list the name, title, rate per hour and number of hours proposed. If a pool of personnel is proposed, list the composition of the pool and how the cost proposed was calculated. List the factor used for prorating Year One and the escalation rate applied between years.

Offeror's proposal should be stated in the same terms as will be used to account for and record direct labor under a contract (i.e. percentage of effort is used for most faculty and professional employees at educational institutions). If percentages of effort are used, the basis to which such percentages are applied must also be submitted by the offeror. The attached format should be revised to accommodate direct labor proposed as a percentage of effort.

b. For all materials, supplies, and other direct costs, list all unit prices, etc., to detail how the calculations were made.

c. For all indirect costs, list the rates applied and the base the rate is applied to.

d. For all travel, list the specifics for each trip.

e. For any subcontract proposed, submit a separate breakdown format.

f. Justification for the need of some cost elements may be listed as an attachment, i.e.,

special equipment, above average consultant fees, etc.

4. If the Government has provided "uniform pricing assumptions" for this solicitation, the offeror must comply with and identify each item.

An electronic spreadsheet is available to assist you in the preparation of your business proposal. It is in EXCEL format and has instructions for use and submission. Prior to using this spreadsheet discuss it with the cognizant Contract Specialist responsible for the RFP of interest to you.

ELECTRONIC CONTRACT BUSINESS PROPOSAL

(http://oamp.od.nih.gov/Division/DFAS/spshexel_Dec2012.xlsx) IMPORTANT

NOTE: Save this file on your computer before opening, otherwise, you will be prompted for a user name and a password and you will lose all the data you may have inserted.

FORMAT:

RFP Number:

Organization:

Date:

BREAKDOWN OF PROPOSED ESTIMATED COST (PLUS FEE) AND LABOR HOURS

COST ELEMENT		Year 1	Year 2	Total
DIRECT LABOR:	<u>Rate</u>	Hours Amt.	Hours Amt.	Hours Amt.
Labor Category				
(Title and Name-- use additional pages as necessary)				
DIRECT LABOR COST		\$ _____	\$ _____	\$ _____
MATERIAL COST		\$ _____	\$ _____	\$ _____
TRAVEL COST		\$ _____	\$ _____	\$ _____

OTHER (Specify)	\$ _____	\$ _____	\$ _____
OTHER (Specify)	\$ _____	\$ _____	\$ _____
TOTAL DIRECT COST	\$ _____	\$ _____	\$ _____
FRINGE BENEFIT COST (if applicable) % of Direct Labor Cost	\$ _____	\$ _____	\$ _____
INDIRECT COST % of Total Direct Cost	\$ _____	\$ _____	\$ _____
TOTAL COST	\$ _____	\$ _____	\$ _____
FEE: (if applicable) % of Total Est. Cost	\$ _____	\$ _____	\$ _____
<u>GRAND TOTAL ESTIMATED COST (PLUS FIXED FEE)</u>	\$ _____	\$ _____	\$ _____

[contracts/update.htm]

OFFEROR'S POINTS OF CONTACT

Complete the following and return with the **BUSINESS PROPOSAL**.

Business Representative

(Name, Title, Address and Contact Information of individual with whom daily contact is required.)*

Name:	Telephone:
Title:	Fax:
Office:	E-Mail:
Organization:	
*Street Address:	
City, State, Zip Code:	

Proposed Principal Investigator

(Name, Institutional Title, Address, and Contact Information)

Name:	Telephone:
Title:	Fax:
Office:	E-Mail:
Organization:	
*Street Address:	
City, State, Zip Code:	

These exact addresses are necessary to ensure that contact can be made with the proper individual(s) in the most expeditious manner.

*Please use actual street address, not P.O. Box.

CERTIFICATE OF CURRENT COST OR PRICING DATA (FAR 15.406-2)

This is to certify that, to the best of my knowledge and belief, the cost or pricing data (as defined in section 2.101 of the Federal Acquisition Regulation (FAR) and required under FAR subsection 15.403-4) submitted, either actually or by specific identification in writing, to the Contracting Officer or to the Contracting Officer's representative in support of _____*
are accurate, complete, and current as of _____**.

This certification includes the cost or pricing data supporting any advance agreements and forward pricing rate agreements between the offeror and the Government that are part of the proposal.

Firm: _____

Signature: _____

Name: _____

Title: _____

Date of execution*** _____

- * Identify the proposal, request for price adjustment, or other submission involved, giving the appropriate identifying number (e.g., RFP No.)
- ** Insert the day, month, and year when price negotiations were concluded and price agreement was reached, or, if applicable, an earlier date agreed upon between the parties that is as close as practicable to the date of agreement on price.
- *** Insert the day, month, and year of signing, which should be as close as practicable to the date when the price negotiations were concluded and the contract price was agreed to.

(End of Certificate)

DISCLOSURE OF LOBBYING ACTIVITIES

Complete this form to disclose lobbying activities pursuant to 31 U.S.C. 1352

Approved by OMB

0348-0046

(See reverse for public burden disclosure.)

1. Type of Federal Action: <input type="checkbox"/> a. contract <input type="checkbox"/> b. grant <input type="checkbox"/> c. cooperative agreement <input type="checkbox"/> d. loan <input type="checkbox"/> e. loan guarantee <input type="checkbox"/> f. loan insurance	2. Status of Federal Action: <input type="checkbox"/> a. bid/offer/application <input type="checkbox"/> b. initial award <input type="checkbox"/> c. post-award	3. Report Type: <input type="checkbox"/> a. initial filing <input type="checkbox"/> b. material change For Material Change Only: year _____ quarter _____ date of last report _____
4. Name and Address of Reporting Entity: <input type="checkbox"/> Prime <input type="checkbox"/> Subawardee Tier _____, if known: Congressional District, if known: ^{4c}	5. If Reporting Entity in No. 4 is a Subawardee, Enter Name and Address of Prime: Congressional District, if known:	
6. Federal Department/Agency:	7. Federal Program Name/Description: CFDA Number, if applicable: _____	
8. Federal Action Number, if known:	9. Award Amount, if known: \$	
10. a. Name and Address of Lobbying Registrant <i>(if individual, last name, first name, MI):</i>	b. Individuals Performing Services <i>(including address if different from No. 10a)</i> <i>(last name, first name, MI):</i>	
11. Information requested through this form is authorized by title 31 U.S.C. section 1352. This disclosure of lobbying activities is a material representation of fact upon which reliance was placed by the tier above when this transaction was made or entered into. This disclosure is required pursuant to 31 U.S.C. 1352. This information will be available for public inspection. Any person who fails to file the required disclosure shall be subject to a civil penalty of not less than \$10,000 and not more than \$100,000 for each such failure.	Signature: _____ Print Name: _____ Title: _____ Telephone No.: _____ Date: _____	
Federal Use Only:		Authorized for Local Reproduction Standard Form LLL (Rev. 7-97)

INSTRUCTIONS FOR COMPLETION OF SF-LLL, DISCLOSURE OF LOBBYING ACTIVITIES

This disclosure form shall be completed by the reporting entity, whether subawardee or prime Federal recipient, at the initiation or receipt of a covered Federal action, or a material change to a previous filing, pursuant to title 31 U.S.C. section 1352. The filing of a form is required for each payment or agreement to make payment to any lobbying entity for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with a covered Federal action. Complete all items that apply for both the initial filing and material change report. Refer to the implementing guidance published by the Office of Management and Budget for additional information.

1. Identify the type of covered Federal action for which lobbying activity is and/or has been secured to influence the outcome of a covered Federal action.
2. Identify the status of the covered Federal action.
3. Identify the appropriate classification of this report. If this is a followup report caused by a material change to the information previously reported, enter the year and quarter in which the change occurred. Enter the date of the last previously submitted report by this reporting entity for this covered Federal action.
4. Enter the full name, address, city, State and zip code of the reporting entity. Include Congressional District, if known. Check the appropriate classification of the reporting entity that designates if it is, or expects to be, a prime or subaward recipient. Identify the tier of the subawardee, e.g., the first subawardee of the prime is the 1st tier. Subawards include but are not limited to subcontracts, subgrants and contract awards under grants.
5. If the organization filing the report in item 4 checks "Subawardee," then enter the full name, address, city, State and zip code of the prime Federal recipient. Include Congressional District, if known.
6. Enter the name of the Federal agency making the award or loan commitment. Include at least one organizational level below agency name, if known. For example, Department of Transportation, United States Coast Guard.
7. Enter the Federal program name or description for the covered Federal action (item 1). If known, enter the full Catalog of Federal Domestic Assistance (CFDA) number for grants, cooperative agreements, loans, and loan commitments.
8. Enter the most appropriate Federal identifying number available for the Federal action identified in item 1 (e.g., Request for Proposal (RFP) number; Invitation for Bid (IFB) number; grant announcement number; the contract, grant, or loan award number; the application/proposal control number assigned by the Federal agency). Include prefixes, e.g., "RFP-DE-90-001."
9. For a covered Federal action where there has been an award or loan commitment by the Federal agency, enter the Federal amount of the award/loan commitment for the prime entity identified in item 4 or 5.
10. (a) Enter the full name, address, city, State and zip code of the lobbying registrant under the Lobbying Disclosure Act of 1995 engaged by the reporting entity identified in item 4 to influence the covered Federal action.

(b) Enter the full names of the individual(s) performing services, and include full address if different from 10 (a). Enter Last Name, First Name, and Middle Initial (MI).
11. The certifying official shall sign and date the form, print his/her name, title, and telephone number.

According to the Paperwork Reduction Act, as amended, no persons are required to respond to a collection of information unless it displays a valid OMB Control Number. The valid OMB control number for this information collection is OMB No. 0348-0046. Public reporting burden for this collection of information is estimated to average 10 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Office of Management and Budget, Paperwork Reduction Project (0348-0046), Washington, DC 20503.

INVOICE INSTRUCTIONS FOR NIH FIXED-PRICE CONTRACTS, NIH(RC)-2

Format: Submit payment requests on Standard Form 1034, Public Voucher for Purchases and Services Other Than Personal, or the Contractor's self-generated form provided it contains all of the information prescribed herein. DO NOT include a cover letter with the payment request.

Number of Copies: Submit payment requests in the quantity specified in the Invoice Submission Instructions in Section G of the Contract Schedule.

Frequency: Submit payment requests upon delivery and acceptance of goods or services unless otherwise authorized by the Contracting Officer.

Currency: All NIH contracts are expressed in United States dollars. When the Government pays in a currency other than United States dollars, billings shall be expressed, and payment by the Government shall be made, in that other currency at amounts coincident with actual costs incurred. Currency fluctuations may not be a basis of gain or loss to the Contractor. Notwithstanding the above, the total of all invoices paid under this contract may not exceed the United States dollars authorized.

Preparation and Itemization of the Payment Request: Prepare payment requests as follows:

Note: *All information must be legible or the invoice will be considered improper and returned to the Contractor.*

- (a) **Designated Billing Office Name and Address:** Enter the designated billing office name and address, as identified in the Invoice Submission Instructions in Section G of the Contract Schedule.
- (b) **Contractor's Name, Address, Point of Contact, TIN, and DUNS or DUNS+4 Number:** Show the Contractor's name and address exactly as they appear in the contract. Any invoice identified as improper will be sent to this address. Also include the name, title, phone number, and e-mail address of the Point of Contact in case of questions. If the remittance name differs from the legal business name, both names must appear on the invoice. Provide the Contractor's Federal Taxpayer Identification Number (TIN) and Data Universal Numbering System (DUNS) or DUNS+4 number. The DUNS number must identify the Contractor's name and address exactly as stated in the contract, and as registered in the System for Acquisition Management (SAM) database.

When an approved assignment of claims has been executed, the Contractor shall provide the same information for the assignee as is required for the Contractor (i.e., name, address, point of contact, TIN, and DUNS number), with the remittance information clearly identified as such.

- (c) **Invoice/Voucher Number:** Identify each payment request by a unique invoice number, which can only be used one time regardless of the number of contracts or orders held by an organization. For example, if a contractor has already submitted invoice number 05 on one of its contracts or orders, it cannot use that same invoice number on any other contract or order. Payment requests with duplicate invoice numbers will be considered improper and returned to the contractor.

The NIH does not prescribe a particular numbering format but suggests using a job or account
NIH(RC)-2
Revised 7/2013

number for each contract and order followed by a sequential invoice number (example: 8675309-05). Invoice numbers are limited to 30 characters. There are no restrictions on the use of special characters, such as colons, dashes, forward slashes, or parentheses.

If all or part of an invoice is suspended and the contractor chooses to reclaim those costs on a supplemental invoice, the contractor may use the same unique invoice number followed by an alpha character, such as "R" for revised (example: 8675309-05R).

- (d) **Date Invoice/Voucher Prepared:** Insert the date the payment request is prepared.
- (e) **Contract Number and Order Number (if applicable):** Insert the contract number and order number (as applicable).
- (f) **Contract Title:** Insert the contract title listed on the cover page of the contract and/or Section G of the Contract Schedule.
- (g) **Current Contract Period of Performance:** Insert the contract start date/effective date through the current completion date of the contract.
- (h) **Total Fixed-Price of Contract/Order:** Insert the total fixed-price of the contract/order.
- (i) **Two-Way/Three-Way Match:** Identify whether payment is to be made using a two-way or three-way match. To determine required payment method, refer to the Invoice Submission Instructions in Section G of the Contract Schedule.
- (j) **Office of Acquisitions:** Insert the name of the Office of Acquisitions, as identified in the Invoice Submission Instructions in Section G of the Contract Schedule.
- (k) **Central Point of Distribution:** Identify the Central Point of Distribution, as specified in the Invoice Submission Instructions in Section G of the Contract Schedule.
- (l) **Billing Period:** Insert the beginning and ending dates (month, day, and year) of the period in which costs were incurred and for which reimbursement is claimed.
- (m) **Description of Supplies or Services:** Provide a description of the supplies or services, by line item (if applicable), quantity, unit price (where appropriate), and total amount. The item description, unit of measure, and unit price **must match** those specified in the contract. For example, if the contract specifies 1 box of hypodermic needles (100/box) with a unit price of \$50.00, then the invoice must state 1 box, hypodermic needles (100/box), \$50.00, **not** 100 syringes at \$0.50 each. Invoices that do not match the line item pricing in the contract will be considered improper and will be returned to the Contractor.
- (n) **Amount Billed - Current Period:** Insert the amount claimed for the current billing period, including any adjustments, if applicable. If the Contract Schedule contains separately priced line items, identify the contract line item(s) on the payment request.
- (o) **Amount Billed - Cumulative:** Insert the cumulative amounts claimed to date, including any adjustments as applicable. If the Contract Schedule contains separately priced line items,

identify the contract line item(s) on the payment request.

(p) **Freight or Delivery Charges:** Identify all charges for freight or express shipments, other than f.o.b. destination, as a separate line item on the invoice. (If shipped by freight or express, and charges are more than \$25, attach prepaid bill.)

(q) **Government Property:** If the contract authorizes the purchase of any item of Government Property (e.g., equipment), the invoice must list each item for which reimbursement is requested. Include reference to the following (as applicable):

- item number for the specific piece of equipment listed in the Property Schedule, and
- Contracting Officer Authorization (COA) Number, if the equipment is not covered by the Property Schedule.

INVOICE/FINANCING REQUEST AND CONTRACT FINANCIAL REPORTING INSTRUCTIONS
FOR NIH COST-REIMBURSEMENT CONTRACTS, NIH(RC)-4

Format: Submit payment requests on the Contractor's self-generated form in the manner and format prescribed herein and as illustrated in the Sample Invoice/Financing Request. Standard Form 1034, Public Voucher for Purchases and Services Other Than Personal, may be used in lieu of the Contractor's self-generated form provided it contains all of the information shown on the Sample Invoice/Financing Request. DO NOT include a cover letter with the payment request.

Number of Copies: Submit payment requests in the quantity specified in the Invoice Submission Instructions in Section G of the Contract Schedule.

Frequency: Payment requests shall not be submitted more frequently than once every two weeks in accordance with the Allowable Cost and Payment Clause incorporated into this contract. Small business concerns may submit invoices/financing requests more frequently than every two weeks.

Cost Incurrence Period: Costs incurred must be within the contract performance period or covered by precontract cost provisions.

Billing of Costs Incurred: : If billed costs include (1) costs of a prior billing period, but not previously billed, or (2) costs incurred during the contract period and claimed after the contract period has expired, the Contractor shall cite the amount(s) and month(s) in which the costs were incurred.

Contractor's Fiscal Year: Prepare payment requests in such a manner that the Government can identify costs claimed with the Contractor's fiscal year.

Currency: All NIH contracts are expressed in United States dollars. When the Government pays in a currency other than United States dollars, billings shall be expressed, and payment by the Government shall be made, in that other currency at amounts coincident with actual costs incurred. Currency fluctuations may not be a basis of gain or loss to the Contractor. Notwithstanding the above, the total of all invoices paid under this contract shall not exceed the United States dollars authorized.

Costs Requiring Advance Approval: Costs requiring advance approval by the Contracting Officer, which are not set forth in the Contract Schedule shall be identified by the Contracting Officer's Authorization (COA) Number as a separate expenditure category on the payment request. In addition, the Contractor shall show any cost limitation or ceiling set forth in the Contract Schedule, i.e. an Advance Understanding, as a separate expenditure category on the payment request.

Invoice/Financing Request Identification: Identify each payment as either:

- (a) **Interim Invoice/Contract Financing Request:** These are interim payment requests submitted during the contract performance period.
- (b) **Completion Invoice:** Submit the completion invoice promptly upon completion of the work, but no later than one year from the contract completion date, or within 120 days after settlement of the final indirect cost rates covering the year in which the contract is physically complete (whichever date is later). The Contractor shall submit the completion invoice when all costs have been assigned to the contract and all performance provisions have been completed.
- (c) **Final Invoice:** A final invoice may be required after the amounts owed have been settled between the Government and the Contractor (e.g., resolution of all suspensions and audit exceptions).

Preparation and Itemization of the Invoice/Financing Request:

The Contractor shall furnish the information set forth in the instructions below. The instructions are keyed to the entries on the Sample Invoice/Financing Request. ***All information must be legible or the invoice will be considered improper and returned to the Contractor.***

- (a) **Designated Billing Office Name and Address:** Enter the designated billing office name and address, as identified in the Invoice Submission Instructions in Section G of the Contract Schedule.
- (b) **Contractor's Name, Address, Point of Contact, TIN, and DUNS or DUNS+4 Number:** Show the Contractor's name and address exactly as they appear in the contract. Any invoice identified as improper will be sent to this address. Also include the name, title, phone number, and e-mail address of the Point of Contact in case of questions. If the remittance name differs from the legal business name, both names must appear on the invoice. Provide the Contractor's Federal Taxpayer Identification Number (TIN) and Data Universal Numbering System (DUNS) or DUNS+4 number. The DUNS number must identify the Contractor's name and address exactly as stated in the contract, and as registered in the System for Award Management (SAM) database.

When an approved assignment of claims has been executed, the Contractor shall provide the same information for the assignee as is required for the Contractor (i.e., name, address, point of contact, TIN, and DUNS number), with the remittance information clearly identified as such.

- (c) **Invoice/Financing Request Number:** Identify each payment request by a unique invoice number, which can only be used one time regardless of the number of contracts or orders held by an organization. For example, if a contractor has already submitted invoice number 05 on one of its contracts or orders, it cannot use that same invoice number on any other contract or order. Payment requests with duplicate invoice numbers will be considered improper and returned to the contractor.

The NIH does not prescribe a particular numbering format but suggests using a job or account number for each contract and order followed by a sequential invoice number (example: 8675309-05). Invoice numbers are limited to 30 characters. There are no restrictions on the use of special characters, such as colons, dashes, forward slashes, or parentheses.

If all or part of an invoice is suspended and the contractor chooses to reclaim those costs on a supplemental invoice, the contractor may use the same unique invoice number followed by an alpha character, such as "R" for revised (example: 8675309-05R).

- (d) **Date Invoice/Financing Request Prepared:** Insert the date the payment request is prepared.
- (e) **Contract Number and Order Number (if applicable):** Insert the contract number and order number (as applicable).
- (f) **Contract Title:** Insert the contract title exactly as it appears on the cover page of the contract and/or Section G of the Contract Schedule.
- (g) **Current Contract Period of Performance:** Insert the contract start date/effective date through the current completion date of the contract.

- (h) **Total Estimated Cost of Contract/Order:** Insert the total estimated cost of the contract, exclusive of fee. If billing under an order, insert the total estimated cost of the order, exclusive of fee. For contracts/orders with options or incremental funding provisions, enter the amount currently obligated and available for payment.
- (i) **Total Fixed-Fee:** Insert the total fixed-fee (where applicable). For contracts/orders with options or incremental funding provisions, enter the amount currently obligated and available for payment (where applicable). **Note:** *If the contract provides for another type of Fee, i.e. Award or Incentive Fee, insert the amount available to be earned as identified in the contract and indicate the type of fee to be billed on the payment request.*
- (j) **Two-Way/Three-Way Match:** Identify whether payment is to be made using a two-way or three-way match. To determine required payment method, refer to the Invoice Submission Instructions in Section G of the Contract Schedule.
- (k) **Office of Acquisitions:** Insert the name of the Office of Acquisitions, as identified in the Invoice Submission Instructions in Section G of the Contract Schedule.
- (l) **Central Point of Distribution:** Insert the Central Point of Distribution, as identified in the Invoice Submission Instructions in Section G of the Contract Schedule.
- (m) **Billing Period:** Insert the beginning and ending dates (month, day, and year) of the period in which costs were incurred and for which reimbursement is claimed.
- (n) **Amount Billed - Current Period:** Insert the amount claimed for the current billing period by major cost element, including any adjustments and fee. If the Contract Schedule contains separately priced line items, identify the contract line item(s) on the payment request and include a separate breakdown (by major cost element) for each line item.
- (o) **Amount Billed - Cumulative:** Insert the cumulative amounts claimed by major cost element, including any adjustments and fee. If the Contract Schedule contains separately priced line items, identify the contract line item(s) on the payment request and include a separate breakdown (by major cost element) for each line item.
- (p) **Direct Costs:** Insert the major cost elements. For each element, consider the application of the paragraph entitled "Costs Requiring Prior Approval" on page 1 of these instructions.
- 1) **Direct Labor:** Include salaries and wages paid (or accrued) for direct performance of the contract.

For Level of Effort contracts only, the Contractor shall provide the following information on a separate sheet of paper attached to the payment request:

- hours or percentage of effort and cost by labor category (as specified in the Level of Effort Article in Section F of the Contract Schedule) for the current billing period, and
- hours or percentage of effort and cost by labor category from contract inception through the current billing period. (NOTE: The Contracting Officer may require the Contractor to provide additional breakdown for direct labor, such as position title, employee name, and salary or hourly rate.)

- 2) **Fringe Benefits:** List any fringe benefits applicable to direct labor and billed as a direct cost. Cite the rate(s) used to calculate fringe benefit costs, if applicable.

- 3) **Accountable Personal Property:** Include permanent research equipment and general purpose equipment having a unit acquisition cost of \$1,000 or more, with a life expectancy of more than two years, and sensitive property regardless of cost (see the HHS *Contractor's Guide for Contract of Government Property*). Show permanent research equipment separate from general purpose equipment.

On a separate sheet of paper attached to the payment request, list each item for which reimbursement is requested. Precede the item with an asterisk (*) if the equipment is below the \$1,000 approval level. Include reference to the following (as applicable):

- item number for the specific piece of equipment listed in the Property Schedule, and,
- Contracting Officer Authorization (COA) number, if the equipment is not covered by the Property Schedule.

The Contracting Officer may require the Contractor to provide further itemization of property having specific limitations set forth in the contract.

- 4) **Materials and Supplies:** Include equipment with unit costs of less than \$1,000 or an expected service life of two years or less, and consumable material and supplies regardless of amount.
- 5) **Premium Pay:** List remuneration in excess of the basic hourly rate.
- 6) **Consultant Fee:** List fees paid to consultants. Identify consultant by name or category as set forth in the contract or COA, as well as the effort (i.e., number of hours, days, etc.) and rate billed.
- 7) **Travel:** Include domestic and foreign travel. Foreign travel is travel outside of the United States and its territories and possessions. However, for an organization located outside the United States and its territories and possessions, foreign travel means travel outside that country. Foreign travel must be billed separately from domestic travel.
- 8) **Subcontract Costs:** List subcontractor(s) by name and amount billed.
- 9) **Other:** List all other direct costs in total unless exceeding \$1,000 in amount. If over \$1,000, list cost elements and dollar amounts separately. If the contract contains restrictions on any cost element, that cost element must be listed separately.
- (q) **Cost of Money (COM):** Cite the COM factor and base in effect during the time the cost was incurred and for which reimbursement is claimed.
- (r) **Indirect Costs:** Identify the indirect cost base (IDC), indirect cost rate, and amount billed for each indirect cost category.
- (s) **Fixed-Fee:** Cite the formula or method of computation for fixed-fee, if applicable. The fixed-fee must be claimed as provided for by the contract. **Note:** *If the contract provides for another type of Fee, i.e. Award or Incentive Fee, provide the same documentation for the amount claimed.*
- (t) **Total Amounts Claimed:** Insert the total amounts claimed for the current and cumulative periods.
- (u) **Adjustments:** Include amounts conceded by the Contractor, outstanding suspensions, and/or disapprovals subject to appeal.

(v) **Grand Totals**

(w) **Certification:** The Contractor shall include the following certification at the bottom of each payment request:

"Pursuant to authority vested in me, I certify that this voucher is correct and proper for payment."

Note: *The contract may require additional certifications (See Invoice Submission Instructions in Section G of the Contract Schedule)*

The Contracting Officer may require the Contractor to submit detailed support for costs claimed on one or more interim payment requests.

FINANCIAL REPORTING INSTRUCTIONS:

These instructions correspond to the Columns on the Sample Invoice/Financing Request.

Column A - Expenditure Category: Enter the expenditure categories required by the contract.

Column B - Cumulative Percentage of Effort/Hrs. - Negotiated: Enter the percentage of effort or number of hours agreed to for each employee or labor category listed in Column A.

Column C - Cumulative Percentage of Effort/Hrs. - Actual: Enter the percentage of effort or number of hours worked by each employee or labor category listed in Column A.

Column D - Amount Billed - Current: Enter amounts billed during the current period.

Column E - Amount Billed - Cumulative: Enter the cumulative amounts to date.

Column F - Cost at Completion: Enter data only when the Contractor estimates that a particular expenditure category will vary from the amount negotiated. Realistic estimates are essential.

Column G - Contract Amount: Enter the costs agreed to for all expenditure categories listed in Column A.

Column H - Variance (Over or Under): Show the difference between the estimated costs at completion (Column F) and negotiated costs (Column G) when entries have been made in Column F. This column need not be filled in when Column F is blank. When a line item varies by plus or minus 10 percent, i.e., the percentage arrived at by dividing Column F by Column G, an explanation of the variance should be submitted. In the case of an overrun (net negative variance), this submission **shall not** be deemed as notice under the Limitation of Cost Clause in the contract.

Modifications: List all new modification(s) (not previously reported) in the amount negotiated for an item in the appropriate cost category.

Expenditures Not Negotiated: An expenditure for an item for which no amount was negotiated (e.g., at the discretion of the Contractor in performance of its contract) should be listed in the appropriate cost category and all columns filled in, except for G. Column H will of course show a 100 percent variance and will be explained along with those identified under H above.

Safety and Health (December 18, 2015)

(a) To help ensure the protection of the life and health of all persons, and to help prevent damage to property, the Contractor shall comply with all Federal, State, and local laws and regulations applicable to the work being performed under this contract. These laws are implemented or enforced by the Environmental Protection Agency, Occupational Safety and Health Administration (OSHA) and other regulatory/enforcement agencies at the Federal, State, and local levels.

(1) In addition, the Contractor shall comply with the following regulations when developing and implementing health and safety operating procedures and practices for both personnel and facilities involving the use or handling of hazardous materials and the conduct of research, development, or test projects:

(i) *29 CFR 1910.1030, Bloodborne pathogens; 29 CFR 1910.1450, Occupational exposure to hazardous chemicals in laboratories; and other applicable occupational health and safety standards issued by OSHA and included in 29 CFR part 1910. These regulations are available at <https://www.osha.gov/>.*

(ii) Nuclear Regulatory Commission Standards and Regulations, pursuant to the Energy Reorganization Act of 1974 (**42 U.S.C. 5801 et seq.**). The Contractor may obtain copies from the **U.S. Nuclear Regulatory Commission**, Washington, DC 20555-0001.

(2) The following Government guidelines are recommended for developing and implementing health and safety operating procedures and practices for both personnel and facilities:

(i) Biosafety in Microbiological and Biomedical Laboratories, CDC. This publication is available at <http://www.cdc.gov/biosafety/publications/index.htm>.

(ii) Prudent Practices for Safety in Laboratories (1995), National Research Council, National Academy Press, 500 Fifth Street, NW., Lockbox 285, Washington, DC 20055 (ISBN 0-309-05229-7). This publication is available at <http://www.nap.edu/catalog/4911/prudent-practices-in-the-laboratory-handling-and-disposal-of-chemicals>.

(b) Further, the Contractor shall take or cause to be taken additional safety measures as the Contracting Officer, in conjunction with the Contracting Officer's Representative or other appropriate officials, determines to be reasonably necessary. If compliance with these additional safety measures results in an increase or decrease in the cost or time required for performance of any part of work under this contract, the Contracting Officer will make an equitable adjustment in accordance with the applicable "Changes" clause set forth in this contract.

(c) The Contractor shall maintain an accurate record of, and promptly report to the Contracting Officer, all accidents or incidents resulting in the exposure of persons to toxic substances, hazardous materials or hazardous operations; the injury or death of any person; or damage to property

incidental to work performed under the contract resulting from toxic or hazardous materials and resulting in any or all violations for which the Contractor has been cited by any Federal, State or local regulatory/enforcement agency. The report citing all accidents or incidents resulting in the exposure of persons to toxic substances, hazardous materials or hazardous operations; the injury or death of any person; or damage to property incidental to work performed under the contract resulting from toxic or hazardous materials and resulting in any or all violations for which the Contractor has been cited shall include a copy of the notice of violation and the findings of any inquiry or inspection, and an analysis addressing the impact these violations may have on the work remaining to be performed. The report shall also state the required action(s), if any, to be taken to correct any violation(s) noted by the Federal, State, or local regulatory/enforcement agency and the time frame allowed by the agency to accomplish the necessary corrective action.

(d) If the Contractor fails or refuses to comply with the Federal, State or local regulatory/enforcement agency's directive(s) regarding any violation(s) and prescribed corrective action(s), the Contracting Officer may issue an order stopping all or part of the work until satisfactory corrective action (as approved by the Federal, State, or local regulatory/enforcement agencies) has been taken and documented to the Contracting Officer. No part of the time lost due to any such stop work order shall form the basis for a request for extension or costs or damages by the Contractor.

(e) The Contractor shall insert the substance of this clause in each subcontract involving toxic substances, hazardous materials, or hazardous operations. The Contractor is responsible for the compliance of its subcontractors with the provisions of this clause.

(End of clause)

SAMPLE TASK ORDER REQUEST FOR PROPOSAL #1

NOTE: THIS IS ONLY A SAMPLE - NO TASK ORDER AWARD WILL BE MADE IN RESPONSE TO THIS REQUEST

Contractor: _____ TBD _____

Contract No: _____ TBD _____

TORP No: 1 Modification No: _____

Order Title: Pharmacokinetics and Bioavailability Evaluations of Selected Anticancer Compounds in Mice

Order Originator: _____ Date Prepared: _____

Task Order Type: Cost Reimbursement (CR)

Part I. INITIATOR'S REQUEST

A. Period of Performance: TO BE DETERMINED

B. Statement of Work/Protocol/Project Description:

The purpose of this Task Order is to rapidly characterize the plasma pharmacokinetics and bioavailability of candidate anticancer compounds in mice as outlined below.

For the base period:

1. Use a standard LC-MS/MS bioanalytical approach, as directed by the COR, for quantification of a small drug-like molecule in mouse plasma. A "generic" assay platform is acceptable and validation to full FDA bioanalytical guidance is not required. An internal standard will be identified and used as a measure of acceptable assay performance. An LLOQ of <10 ng/mL is desirable.
2. Carry out the appended protocol for mouse PK and bioavailability evaluations with a small drug-like compound to be provided by NCI. Note for costing purposes that the protocol specifies 2 dose groups with two routes of administration, 8 time points, and 3 mice/time point, for a total of 48 plasma samples to be generated for analysis.
3. Pharmacokinetic data analysis should include standard non-compartmental modeling to determine $C_{max}(po)$, $C_0(iv)$, T_{max} , $AUC_{0-\infty}$, AUC_{last} , CL, and $t_{1/2}$, V_{ss} , and %F for each compound.

For Options 1 - 9:

1. Perform PK-bioavailability evaluations as above and per the attached protocol for one additional compound per option. Minor adjustments to the protocol that should not affect cost or schedule (e.g., routes of administration, specific sampling times) may be made. Options are considered additional quantities and are not directly related to specific dates. Options may be exercised at any time within the Task Order period of performance.

C. Deliverables:

- A fully signed protocol shall be provided to the COR prior to initiation of each evaluation.
- Summary data in tabular form (c vs. t and PK parameters, with suitable plots) for each compound shall be provided to the COR within two weeks of receipt of that compound.
- Separate draft reports for the base period and for each of any options exercised will be due two weeks after completion of each evaluation. The reports will accurately and completely describe

the experimental design and methods and present an analysis/summary of the data followed by the conclusions derived from the analyses.

- The final report will be due two weeks after return of the draft report for revision.

D. Additional Instructions:

As Task Orders may be competed among the contractors if multiple awards are made pursuant to this RFP, please consider and provide information in your response to address Items E and F.

E. Evaluation Factors:

Proposals will be evaluated on the following factors, in order of importance:

- 1) Turn-around time (weight 50%): Documented ability to perform protocol designated evaluations rapidly and submit summary data in tabular form (c vs. t and PK parameters) for each compound within two weeks of receipt of that compound. Evidence of experience and creativity in scheduling assigned work to meet or exceed on-time goals.
- 2) Cost (weight 40%): Reasonableness of labor mix, proposed hours, and total costs.
- 3) Technical (weight 10%): Ability to rapidly implement suitable LC/MS-MS methods for small drug-like molecules and apply them to analysis of plasma samples. Understanding of appropriate analytical method and validation procedures in context with experimental goals and the state of compound development (e.g., early screening PK vs. full GLP evaluations). Constructive suggestions on design elements in the attached protocol. Evidence of submission of complete, well-organized, and high-quality technical reports.

F. Order Response:

The Technical Proposal shall be 3-4 pages in length and consist of an outline of your approach to appended protocol. Specific procedural recommendations and/or alternative methods may be recommended. Include a proposed timeline for the work from protocol approval to submission of the final report. Briefly highlight your relevant experience with appropriate analytical method development and performing pharmacokinetic evaluations on similar timelines.

The Business Response shall at least include a Coversheet and a Budget (provided substantially as indicated in Part II of this form). The Coversheet shall at least consist of:

- RFP Number
- Task Order RFP Number
- Name, address, email and telephone number of point of contact
- Name, address, email and telephone number of contract Administration Office (if applicable)
- Date of submission
- Name, title, address, email, telephone and signature of authorized Business Representative (person authorized to sign contracts on behalf of the organization).

Budgets for the base period and each Option should be provided separately. Note: this Order will initially be awarded for the base period and associated costs to conduct the appended protocol. The Government may decide to unilaterally exercise and fund one or more Options for additional work as listed above. A notice of intent to exercise each option would be sent seven days prior to unilateral exercise.

G. Order Response Due Date: Responses to this Task Order should be included in your technical and business proposals for this RFP

TASK ORDER REQUEST FOR PROPOSAL (TORP)

Contractor: _____ [fill in] _____ Contract No: _____

TORFP No: 1 Modification No: 0 Date Prepared: _____

Part II. CONTRACTOR'S RESPONSE TO ORDER REQUEST

(*The Contractor shall attach a detailed budget to this form to identify all proposed costs.)

A. Estimated Cost and Effort:

1. Labor hours – list order leader, specific individuals to be assigned, labor category, and estimated hours for each.
2. Labor costs – list by labor category and total.
3. Employee benefits.
4. Direct materials.
5. Travel.
6. Subcontracts.
7. Other direct costs.
8. Indirect costs.
9. Total estimated costs for this Order: _____*

B. Detailed description of the approach to be used and of the deliverable(s). (Be specific):

APPROVAL TO PROCEED: The Contractor shall not exceed the estimated labor hours, estimated Order amount, or change the Order leader without the prior written approval of the Contracting Officer's Representative and the Contracting Officer.

1. For the Contractor: _____ Date: _____
(Signature)

Typed Name: _____

2. For the Government: _____ Date: _____
Contracting Officer's Representative (COR)

_____ Date: _____
Contracting Officer

SAMPLE PROTOCOL
TASK ORDER #1

PHARMACOKINETICS AND ORAL BIOAVAILABILITY OF [NSC TBD] IN MALE MICE

SPONSOR: Toxicology and Pharmacology Branch
Developmental Therapeutics Program
Division of Cancer Treatment and Diagnosis
National Cancer Institute
National Institutes of Health
Bethesda, Maryland 20892

COR: TBD

CONTRACT NUMBER: TBD

CONTRACTOR: TBD

PROJECT MANAGER: TBD

PROJECT DIRECTOR: TBD

PROPOSED IN-LIFE PHASE:

Start: TBD

Finish: TBD

I. OBJECTIVE

The objective of this protocol is to characterize the plasma pharmacokinetics and oral bioavailability of NSC TBD in male mice.

II. MATERIALS AND METHODS**A. Test Article and Vehicle:**

1. **Name of Test Article:**
NSC TBD
2. **Name of Vehicle:**
TBD
3. **Characterization and Documentation of Methods of Synthesis, Fabrication or Derivation:**
 - a. **Test Article:**
Compound identity, strength, quality, stability and purity as well as documentation of methods of synthesis, fabrication or derivation are the responsibility of the NCI. Sufficient quantity of drug shall be reserved for archiving from each lot and shipment used.
 - b. **Vehicle:**
The vehicles are stable throughout the date of expiration on the container labels when stored according to the manufacturer's instructions.

B. Test System:

1. **Species, Strain Supplier and Test System Justification:**
CD-1 mice or other acceptable strain obtained from an approved commercial supplier will be used in this evaluation. This is an accepted species to support studies of compounds used or intended for use in humans.
2. **Initial Age, Sex and Weight:**
On the first day of dosing, the weight ranges of mice will be approximately 18 to 22 grams and the mice will be approximately 5 to 7 weeks of age. Only males will be used.
3. **Care and Housing:**
General procedures for animal care and housing will be in accordance with The Guide for the Care and Use of Laboratory Animals, National Research Council, 2011 and the U.S. Department of Agriculture through the Animal Welfare Act (7 USC

2131), 1985 and Animal Welfare; Standards incorporated in 9 CFR Part 3, 1991. Appropriate caging and bedding or cage board (not cedar or pine chips) will be used. No contaminants shall be present in the bedding which could interfere and affect the results of the evaluation. Environmental parameters will be set to maintain conditions specified in the facility SOPs. Environmental conditions will be within specified limits of at least 90 percent of scheduled observations.

4. Diet and Water Supply:

Diet is to be certified, commercial, dry rodent chow provided *ad libitum*. Water source will be the public supply given *ad libitum*. No contaminants will be present in the feed or water which could interfere and affect the results of the evaluation.

5. Quarantine:

All mice will be quarantined for a minimum of 5 days prior to baseline measurements. No prophylactic or therapeutic treatment will be administered during the quarantine period. Only healthy animals will be placed on test.

6. Animal Identification:

All mice will be given a unique identification number for this evaluation by ear tag or other approved method.

C. Experimental Design

1. Randomization:

In order to obtain groups that are comparable by weight, all mice will be randomly assigned from the colony to each treatment group using a computer-based body weight stratification procedure.

2. Group Assignments:

After randomization, 12 male mice will be assigned to each of two dose groups as follows:

Group	Cpd.	Route	Dose (mg/kg)	Conc. in Formulation (mg/mL)	Dose Volume (mL/kg)	Sub-group	No. of Animals	Blood (Plasma) Collection Timepoint (min)
1	NSC TBD	IV	TBD	TBD	5	A	3	5, 120
						B	3	15, 240
						C	3	30, 480
						D	3	60, 1440
2	NSC TBD	PO	TBD	TBD	5	A	3	15, 240
						B	3	30, 360
						C	3	60, 480
						D	3	120, 1440

3. **Route of Administration and Reason for Choice:**
The test compound will be given as a single intravenous or oral dose in order to characterize its pharmacokinetics and bioavailability in mice.
4. **Formulation Preparation:**
To be specified for iv and oral administration to mice.
5. **Dosing Procedure:**
On Day 1, each mouse in a given dose group will receive formulated test article either by iv injection (tail vein) or oral gavage. The dose volume will be 5 mL/kg of body weight. The amount of drug administered to each mouse will be based on each animal's most recent individual body weight.
6. **Measurements:**
 - a. **Clinical signs:**
The mice will be observed during the blood sampling period and any adverse clinical signs recorded.
 - b. **Body Weight:**
Individually weigh all mice prior to dosing on Day 1.
 - c. **Sample Collection for Plasma Drug Levels:**
Whole blood samples (target volume of 200 μ L) will be collected from 4 cohorts of 3 mice each from each group via the retro-orbital sinus (or other proposed method). Mice in each cohort will be stagger-sampled twice to obtain the eight timepoints indicated below and in the table above. Mice will be anesthetized and blood will be collected according to established laboratory SOPs. Blood will be placed into tubes containing the anticoagulant EDTA.

Target blood collection time points:

Group 1 (iv): 5, 15, 30, 60, 120, 240, 480, and 1440 minutes after dosing.

Group 2 (oral): 15, 30, 60, 120, 240, 360, 480, and 1440 minutes after dosing.

Actual collection times will be recorded.

Blood samples will be placed on wet ice until centrifuged to obtain plasma. Plasma samples will be transferred into appropriately labeled tubes and placed on dry ice until stored in a freezer set to maintain at least -70 °C.

- e. **Necropsy Procedure:**
Necropsy is not required in this protocol.
- d. **Bioanalytical and Pharmacokinetic Analysis:**
A bioanalytical method for the compound in mouse plasma will be implemented using standard LC-MS/MS approaches. Analytical sensitivity shall be as great as possible (ideally < 10 ng/mL). Full validation to FDA guidelines is not required for this analysis.

Total number of samples for quantification of test article in plasma:

8 timepoints x 3 mice/timepoint x 2 groups = 48 samples

Pharmacokinetic data analysis shall include (at a minimum) standard non-compartmental modeling to determine $C_{max}(po)$, $C_0(iv)$, T_{max} , $AUC_{0 \rightarrow \infty}$, AUC_{last} , CL , and $t_{1/2}$, V_{ss} , and %F.

III. QUALITY ASSURANCE

- A. **Type of Evaluation**
This evaluation will not require compliance with the FDA Good Laboratory Practice Regulations.
- B. **Standard Operating Procedures**
All operations pertaining to this evaluation, unless specifically defined in this protocol, will be performed according to the standard operating procedures of the laboratory and any deviations will be documented.
- C. **Protocol Amendments**
All changes in or revisions of an approved protocol and the reasons therefore will be documented, signed, and dated by the Project Director/Project Manager and the NCI COR. Amendments will be maintained with the protocol. Verbal approval for changes in the protocol may be granted by the NCI COR, but a written amendment will follow.

IV. REPORTING AND DISCUSSION OF DATA

- A. **Interim Tabulated Data**
Concentration-time data and derived PK parameters for the test compound shall be provided to the COR in a spreadsheet format, along with suitable c vs. t plots **within two weeks of receipt of the compound.**

B. Final Report

The results obtained under this protocol will be submitted as a draft report, **due two weeks after completion of the evaluation**. This report will accurately and completely describe the experimental design, procedures and findings, present an analysis and summary of the data followed by the conclusions derived from the analyses. The report will also include: (a) a cover page which will include the title, contract number, authors, laboratory address, dates of initiation and completion, and sponsor; (b) an abstract to be placed at the beginning of the final report; (c) a comprehensive summary to be placed after the abstract; (d) the signature of the Project Director/Project Manager and any others deemed necessary; (e) a table of contents. The draft report will be reviewed by the COR and any requests for revisions will be sent to the Project Director/Project Manager. The final report will be due two weeks after return of the draft report for revision.

Protocol Approvals:

Project Director:

(Date)

Project Manager:

(Date)

NCI COR:

(Date)

SAMPLE TASK ORDER REQUEST FOR PROPOSAL #2

NOTE: THIS IS ONLY A SAMPLE - NO TASK ORDER AWARD WILL BE MADE IN RESPONSE TO THIS REQUEST

Contractor: _____ TBD _____

Contract No: _____ TBD _____

TORP No: 2 Modification No: _____Order Title: Pharmacokinetic-Pharmacodynamic-Efficacy Evaluations with Selected Compounds in Human Tumor Xenografts in Nude Mice

Order Originator: _____ Date Prepared: _____

Task Order Type: Cost Reimbursement (CR)**Part I. INITIATOR'S REQUEST**A. Period of Performance: TO BE DETERMINEDB. Statement of Work/Protocol/Project Description:

The purpose of this Task Order is to perform pharmacokinetic-pharmacodynamic-efficacy evaluation(s) with an investigational anticancer agent(s) in a mouse tumor model.

For the base period:

The contractor shall provide all necessary labor and materials to carry out the appended protocol entitled, "Pharmacokinetic-Pharmacodynamic-Efficacy Evaluation of [NSC XXX] in [cell line TBD] Tumor Xenografts in Nude Mice." All collected samples are to be shipped to an NCI-designated laboratory for analysis.

For Options 1 - 5:

For each Option, the contractor shall carry out a protocol similar to that provided for the base period. The test articles and tumor cell lines may be different for each option, but overall designs (number of animals, dosing events, sample collections) will be similar. Options are considered additional quantities and may be exercised anytime during the Task Order Period of Performance.

C. Deliverables:

- A fully signed protocol shall be provided to the COR prior to initiation of the evaluation, along with evidence of IACUC approval.
- Data collected (animal weights, clinical observations, etc.) to be provided in Excel (or other agreed upon format) within 5 working days after the end of the in-life phase.
- Collected samples will be shipped to the protocol-designated laboratory. Sample collection information and inventory to be provided with shipment and copied to the COR electronically.
- Separate reports for the base and all options exercised. Each report shall include methods, in-life observations, and any problems or deviations encountered. Draft reports will be due 14 working days after the last sample is collected. The final report will be due 14 working days after return of the draft report for revision.

D. Additional Instructions:

As Task Orders may be competed among the contractors if multiple awards are made pursuant to this RFP, please consider and provide information in your response to address Items E and F.

E. Evaluation Factors:

Proposals will be evaluated on the following factors, in order of importance:

- 1) Technical (Weight 40%): Demonstrated experience in conducting experiments with human tumor xenograft models in mice. Evidence of technical ability to implant, stage, treat, monitor, and obtain samples from such experiments. Experience in packaging and shipping frozen samples to designated recipients.
- 2) Schedule (Weight 30%): Documented ability and capacity to rapidly initiate xenograft evaluations in mice. Timely delivery of results and dispatch of shipped samples within 5 working days (or earlier) after the end of the in-life phase. Evidence of previous achievement of similar timeline goals.
- 3) Cost (Weight 30%): Reasonableness of labor mix, proposed hours, animal costs, and total costs.

F. Order Response:

The Technical Proposal shall be 3-4 pages in length and consist of an outline of your approach to appended protocol. Specific procedural recommendations and/or alternative methods may be recommended. Include a proposed timeline for the work from protocol approval to submission of the final report.

The Business Response shall at least include a Coversheet and a Budget (provided substantially as indicated in Part II of this form). The Coversheet shall at least consist of:

- RFP Number
- Task Order RFP Number
- Name, address, email and telephone number of point of contact
- Name, address, email and telephone number of contract Administration Office (if applicable)
- Date of submission
- Name, title, address, email, telephone and signature of authorized Business Representative (person authorized to sign contracts on behalf of the organization).

Budgets for the base period and each Option should be provided separately. Note: this Order will initially be awarded for the base period and associated costs to conduct the appended protocol. The Government may decide to unilaterally exercise and fund one or more Options for additional work as listed above. A notice of intent to exercise each option would be sent seven days prior to unilateral exercise.

G. Order Response Due Date: Responses to this Task Order should be included in your technical and business proposals for this RFP.

TASK ORDER REQUEST FOR PROPOSAL (TORP)

Contractor: _____ [fill in] _____ Contract No: _____

TORFP No: 2 Modification No: 0 Date Prepared: _____

Part II. CONTRACTOR's RESPONSE TO ORDER REQUEST*

(*The Contractor shall attach a detailed budget to this form to identify all proposed costs.)

A. Estimated Cost and Effort:

1. Labor hours – list order leader, specific individuals to be assigned, labor category, and estimated hours for each.
2. Labor costs – list by labor category and total.
3. Employee benefits.
4. Direct materials.
5. Travel.
6. Subcontracts.
7. Other direct costs.
8. Indirect costs.
9. Total estimated costs for this Order: _____

B. Detailed description of the approach to be used and of the deliverable(s). (Be specific):

APPROVAL TO PROCEED: The Contractor shall not exceed the estimated labor hours, estimated Order amount, or change the Order leader without the prior written approval of the Contracting Officer's Representative and the Contracting Officer.

1. For the Contractor: _____ Date: _____
(Signature)

Typed Name: _____

2. For the Government: _____ Date: _____
Contracting Officer's Representative (COR)

_____ Date: _____
Contracting Officer

**SAMPLE PROTOCOL
TASK ORDER #2**

**Pharmacokinetic-Pharmacodynamic-Efficacy Evaluation of [NSC(s) XXXXX] in
[Cell Line TBD] Tumor Xenografts in Nude Mice**

SPONSOR: Toxicology and Pharmacology Branch
Developmental Therapeutics Program
Division of Cancer Treatment and Diagnosis
National Cancer Institute
National Institutes of Health
Bethesda, Maryland 20892

MONITOR: TBD

CONTRACT NUMBER: TBD

CONTRACTOR: TBD

PROJECT MANAGER: TBD

PROJECT DIRECTOR: TBD

KEY DATES:

I. OBJECTIVE

The objectives of this evaluation are to determine the efficacy of the LDHA inhibitor(s), NSC(s) XXXXX against [cell line] xenografts in mice and to obtain plasma and tumor samples at various times to characterize the plasma and tumor pharmacokinetics and pharmacodynamics of the compound(s).

II. MATERIALS AND METHODS**A. Test Article and Vehicle:**

1. **Name of Test Article:**
TBD
2. **Vehicle:**
TBD
3. **Characterization and Documentation of Methods of Synthesis, Fabrication or Derivation or test article and vehicle:**
 - a. **Test Article:**
Compound identity, strength, quality, stability and purity and documentation of methods of synthesis, fabrication or derivation are the responsibility of the NCI and will be communicated to the CRO.
 - b. **Vehicle:**
The vehicle (and its components) is stable throughout the date of expiration on the container labels when stored according to the manufacturer's instructions.

B. Test System:

1. **Species, Strain Supplier and Test System Justification:**
Athymic nude (nu/nu NCr) mice obtained from an approved commercial supplier will be used in this evaluation.
2. **Initial Age, Sex and Weight:**
On the first day of dosing, the weight ranges of mice will be approximately 20-24 grams and the mice will be approximately 6 to 7 weeks of age. Only females will be used.
3. **Care and Housing:**
General procedures for animal care and housing will be in accordance with the *Guide for the Care and Use of Laboratory Animals*, National Research Council, 2011 and the U.S. Department of Agriculture through the Animal Welfare Act (Public Law 99-198). Appropriate caging and bedding or cage board (not

cedar or pine chips) will be used. No contaminants shall be present in the bedding that could interfere and affect the results of the evaluation. Environmental parameters will be set to maintain conditions specified in the facility SOPs. Environmental conditions will be within specified limits of at least 90 percent of scheduled observations.

4. Diet and Water Supply:

Diet is to be certified, commercial, dry rodent chow provided *ad libitum*. Water source will be the public supply given *ad libitum*. No contaminants will be present in the feed or water that could interfere and affect the results of the evaluation.

5. Acclimation:

All animals will be isolated upon arrival, and the Attending Veterinarian or designee will document that the animals are healthy and free from disease and parasites. The animals will be acclimated to the housing room for at least 5 days prior to dosing. Only healthy animals will be placed on test.

6. Animal Identification:

All mice will be given a unique identification number by ear punch or other approved method.

7. Human Tumor Xenograft:

Tumor cells will be obtained from the American Type Culture Collection (ATCC) or other approved source. Cells shall be passaged *in vitro* according to the supplier's recommendations. A suspension of 1×10^7 cells shall be implanted subcutaneously in sufficient host animals to conduct the evaluation described below. Tumors will be staged when the median tumor size reaches approximately 200 mg (or a designated size as per NCI direction).

C. Experimental Design

1. Randomization:

In order to obtain groups that are comparable by tumor weight, all mice will be randomly assigned to each treatment group using a computer-based body weight stratification procedure, randomizing for tumor volumes calculated as follows:

$$\text{Tumor volume} = 1/2(\text{length} \times \text{width}^2)$$

2. Group Assignments:

Upon randomization, 59 female mice will be assigned to the vehicle control group and 51 mice will be assigned to each of four treatment groups. Eight mice will be used as untreated controls.

Group	# Mice	Cpd.	Route	Dose (mg/kg)	Conc. in Formulation (mg/mL)	Dose Volume (mL/kg)	Schedule
1	59 (16 for efficacy)	Vehicle	IP	0	0	10	QD x 14
2	51 (8 for efficacy)	NSC 1	IP	Level 1	TBD	10	QD x 14
3	51 (8 for efficacy)	NSC 1	IP	Level 2	TBD	10	QD x 14
4	51 (8 for efficacy)	NSC 2	IP	Level 1	TBD	10	QD x 14
5	51 (8 for efficacy)	NSC 2	IP	Level 2	TBD	10	QD x 14
6	8	Untreated Controls	--	--	--	--	--

3. Route of Administration and Reason for Choice:

The test compound will be given as daily intraperitoneal injections for 14 days in order to characterize the effects on tumor growth and the pharmacokinetic-pharmacodynamic time course in plasma and tumor.

4. Formulation Preparation

[Prepared twice-weekly; detailed procedures to be specified]

5. Dosing Procedure:

All mice in each group will receive either vehicle (Group 1) or formulated test article (Groups 2-5) by intraperitoneal injection on days 1 to 14. The dose volume will be 10 mL/kg of body weight for all dose groups. The amount of drug administered to each mouse will be based on each animal's most recently determined individual body weight.

6. Measurements:

a. Clinical signs:

The mice will be observed at least once daily during the dosing period and at least twice-weekly thereafter. Any adverse clinical signs recorded.

- b. Body Weight:**
Mice shall be weighed prior to dosing each day and the weight shall be used to adjust the dose volume for test article administration.
- c. Tumor Volume:**
Tumor volumes for all mice remaining on study will be measured by caliper at least twice weekly. Note that cohorts of 8 mice/group (16 in control group) will remain after the dosing/sampling period and shall have tumor volume measurements at the above interval until the end of the evaluation (~50-60 days post-implant).
- d. Plasma and Tumor Sample Collection:**
Plasma and tumor samples will be collected as follows:

Day 1 Collections	Harvest tumors from 5 mice in Groups 1-5 at 2, 4, 8, 16, and 24 hr after dose 1 (the latter just prior to dose 2), cut into halves and flash freeze. Collect blood in EDTA tubes at times of sacrifice - spin, flash freeze plasma. Harvest tumor and plasma samples from all Group 6 (untreated) mice at a convenient time on Day 1
Day 4 Collections	Harvest tumors from 3 mice in Groups 1-5 at 2 hr after dose 4 and 24 hours (just prior to dose 5), cut into halves and flash freeze. Collect blood in EDTA tubes at times of sacrifice - spin, flash freeze plasma.
Day 9 Collections	Harvest tumors from 3 mice in Groups 1-5 at 2 hr after dose 9 and 24 hours (just prior to dose 10), cut into halves and flash freeze. Collect blood in EDTA tubes at times of sacrifice - spin, flash freeze plasma.
Day 14 Collections	Harvest tumors from 3 mice in Groups 1-5 at 2 hr and 24 hours after dose 14, cut into halves and flash freeze. Collect blood in EDTA tubes at times of sacrifice - spin, flash freeze plasma.

Actual collection times will be recorded.

Blood samples will be placed on wet ice until centrifuged to obtain plasma. Plasma samples will be transferred into appropriately labeled tubes and placed on dry ice until stored in a freezer set to maintain at least -70 °C until all samples are ready for shipping.

Tumors will be excised from the implant site (according to facility SOP), cut into halves and flash frozen. Each tumor piece will be placed in a separate cryo vial and stored at least -70 °C until all samples are ready for shipping..

- d. Necropsy Procedure:**
Necropsy is not required in this evaluation. Moribund

animals and animals with excessive or necrotic tumor growth will be euthanized according to facility SOP.

e. **Bioanalytical and Pharmacodynamic Analysis:**

Plasma and tumor levels of the test article, as well as pharmacodynamic measurements will be conducted at another NCI-designated facility.

All samples from the evaluation shall be shipped on dry ice in one batch to:

[To be specified in final protocol]

III. **QUALITY ASSURANCE**

A. **Type of Evaluation**

This evaluation will not require compliance with the FDA Good Laboratory Practice Regulations.

B. **Standard Operating Procedures**

All operations pertaining to this evaluation, unless specifically defined in this protocol, will be performed according to the standard operating procedures of the laboratory and any deviations will be documented.

C. **Protocol Amendments**

All changes in or revisions of an approved protocol and the reasons therefore will be documented, signed, and dated by the Project Manager/Project Director and the NCI COR. Amendments will be maintained with the protocol. Verbal approval for changes in the protocol may be granted by the NCI COR, but a written amendment will follow.

IV. **REPORTING AND DISCUSSION OF DATA**

B. **Report and Data Analysis**

All animal related data (clinical observations, body weights or other) will be provided in an excel spreadsheet suitable for post hoc analysis. Documentation of tumor and plasma collection times, sample handling and sample numbers shall be provided in a spreadsheet to be included with the sample shipment and in a duplicate file sent electronically to the NCI COR.

V. REGULATORY REFERENCES

A. Facilities and Animal Husbandry:

Animal care will be in compliance with facility SOPs, the *Guide for the Care and Use of Laboratory Animals*, (Institute of Laboratory Animal Research, Division on Earth and Life Sciences, National Research Council; National Academy Press; Washington, DC; 2011), and the U.S. Department of Agriculture through the Animal Welfare Act (Public Law 99-198).

B. Animal Welfare Act Compliance:

By signing this protocol, the Sponsor signifies that there are no generally accepted alternatives to the use of animals, and that the evaluation described by this protocol does not unnecessarily duplicate previously conducted or reported experiments.

Procedures used in this protocol are designed to conform to accepted practices and to minimize or avoid causing pain, distress, or discomfort in the animals. In those circumstances in which required test procedures are likely to cause more than momentary or slight pain or distress, the animals will receive appropriate analgesics or anesthetics unless the withholding of these agents has been justified in writing by the Project Director and approved by the facility's Institutional Animal Care and Use Committee (IACUC).

C. Safety Compliance:

This evaluation will comply with all applicable federal and state regulations, including the CDC/NIH's BMBL current edition, OSHA standard 1910.1450 "Occupational Exposure to Hazardous Chemical in Laboratories" and by applying recommended best practices or other recognized safe practices and codes. The evaluations will be conducted in a manner that ensures that the health, safety, and welfare of our employees, the public, and the environment are maintained.

Protocol Approvals:

Project Manager/Project Director: _____
TBD Date

NCI's Representative: _____
TBD Date

during the Task Order Period of Performance.

C. Deliverables:

- Interim c vs. t data in spreadsheet format for each compound sent to the COR within 14 working days after receipt of samples.
- Draft analysis report for the base period and separate draft analysis reports for all options exercised. Each report will cover the results for a single compound/sample set, and include sections on the methods used, data obtained (including charts/graphs and tables as appropriate), and analysis/discussion of the results. Draft reports will be due 14 working days after provision of interim data for the base period and any options
- Final analysis reports will be due 7 working days after return of a draft report for revision.

D. Additional Instructions:

As Task Orders may be competed among the contractors if multiple awards are made pursuant to this RFP, please consider and provide information in your response to address Items E and F.

E. Evaluation Factors:

Proposals will be evaluated on the following factors, in order of importance:

- 1) Cost (Weight 40%): Realistic per sample cost based on number of samples/compounds specified; costs shall not be based solely on the total period of performance of the Task Order.
- 2) Schedule (Weight 30%): Documented ability to rapidly initiate method development once notified that samples will be available; timely delivery of initial results and analyses within two weeks from time of sample receipt. Evidence of previous achievement of similar timeline goals.
- 3) Technical (Weight 30%): Demonstrated ability to expeditiously implement LC/MS-MS methods for small drug-like molecules and apply them to analysis of plasma and tumor samples.

F. Order Response: Technical Proposal shall be 3-4 pages in length and consist of a brief summary of your approach to analytical method implementation, the schedule for sample analysis as batches are received, and the relevant experience with similar tasks and timelines.

The Business Response shall at least include a Coversheet and a Budget (provided substantially as indicated in Part II of this form). The Coversheet shall at least consist of:

- RFP number
- Task Order RFP Number
- Name, address, email and telephone number of point of contact
- Name, address, email and telephone number of contract Administration Office (if applicable)
- Date of submission
- Name, title, address, email, telephone and signature of authorized Business Representative (person authorized to sign contracts on behalf of the organization)

Budgets for the base period and each Option shall be provided separately. Note this Order will initially be awarded only for the base period and associated costs for one compound (100 samples). The Government may decide to unilaterally exercise and fund one or more Options for additional analyses as listed above in a sequential manner. A notice of intent to exercise each option will be sent 7 days prior to unilateral exercise.

G. Order Response Due Date: Responses to this Task Order shall be included in your technical and business proposals for this RFP.

TASK ORDER REQUEST FOR PROPOSAL (TORP)

Contractor: _____ [fill in] _____ Contract No: _____

TORFP No: 3 Modification No: 0 Date Prepared: _____

Part II. CONTRACTOR'S RESPONSE TO ORDER REQUEST

(*The Contractor shall attach a detailed budget to this form to identify all proposed fixed-price costs.)

A. Estimated Cost and Effort:

1. Labor hours – list order leader, specific individuals to be assigned, labor category, and estimated hours for each.
2. Labor costs – list by labor category and total.
3. Employee benefits.
4. Direct materials.
5. Travel.
6. Subcontracts.
7. Other direct costs.
8. Indirect costs.
9. Total estimated costs for this Order: _____ *
- 10.

B. Detailed description of the approach to be used and of the deliverable(s). (Be specific):

APPROVAL TO PROCEED: The Contractor shall not exceed the estimated labor hours, estimated Order amount, or change the Order leader without the prior written approval of the Contracting Officer's Representative and the Contracting Officer.

1. For the Contractor: _____ Date: _____
(Signature)

Typed Name: _____

2. For the Government: _____ Date: _____
Contracting Officer's Representative (COR)

_____ Date: _____
Contracting Officer

SAMPLE TASK ORDER REQUEST FOR PROPOSAL #4

NOTE: THIS IS ONLY A SAMPLE - NO TASK ORDER AWARD WILL BE MADE IN RESPONSE TO THIS REQUEST

Contractor: _____TBD_____

Contract No: _____TBD_____

TORP No: 4 Modification No: _____Order Title: Clinical Pharmacology Support for an NCI Phase I Trial of NSC XXXXXTask Order Type: Fixed Price (FP)

Order Originator: _____ Date Prepared: _____

Part I. INITIATOR'S REQUESTA. Period of Performance: TO BE DETERMINEDB. Statement of Work/Protocol/Project Description:

The purpose of this Task Order (TO) is to provide a resource for analytical and pharmacokinetic support to an NCI Phase I clinical trial with NSC XXXXX:

Phase I Trial of NSC XXXXX in Adults with Refractory Solid Tumors

The following specific elements are included:

- Implement appropriately validated LC-MS/MS methodology for the quantification of NSC XXXXX in human plasma and urine.
- Secure all needed internal approval(s) for receipt and analysis of human samples to be generated by this NCI Phase I trial. The clinical protocol and certification of NCI IRB approval will be provided to you.
- Determine levels of NSC XXXXX in human plasma and urine samples obtained from up to 30 patients in the clinical trial. It is anticipated that 12 plasma and 3 urine samples will be collected from each patient in cycle 1 only (= 360 plasma samples and 90 urine samples). Samples sets will be shipped as patients are accrued and treated, so planning for intermittent analyses will be critical. For costing purposes, assume samples will be analyzed in five (5) batches.
- Pharmacokinetic data analysis shall include standard non-compartmental modeling to determine C_{max} , T_{max} , $AUC_{0 \rightarrow \infty}$, AUC_{last} , CL, and $t_{1/2}$, V_{ss} , for each patient. Cumulative urinary excretion and clearance shall also be determined. Population modeling approaches may be also proposed.

C. Deliverables:

- Interim c vs. t data for each patient to be sent to the COR within 14 working days after receipt of samples. Preliminary PK parameter estimates after one additional week.

- Draft bioanalytical and clinical pharmacokinetics report due one month after analysis of the final patient sample set. The final report will be due 14 working days after return of the draft report for revision.

D. Additional Instructions:

As Task Orders may be competed among the contractors if multiple awards are made pursuant to this RFP, please consider and provide information in your response to address Items E and F.

E. Evaluation Factors:

Proposals will be evaluated on the following factors, in order of importance:

- 1) Technical (Weight 40%): Prior experience in implementing and utilizing validated analytical methods for compounds being evaluated in early clinical trials. Experience with pharmacokinetic modeling of concentration-time data in a clinical pharmacology setting. Familiarity with compartmental and population modeling is a plus.
- 2) Schedule (Weight 30%): Demonstrated ability to rapidly perform sample analysis to assure timely delivery of tabulated data within 14 working days from the time of sample receipt. Ability to expeditiously handle intermittent sample shipments, with the possibility of periods with no work.
- 3) Cost (Weight 30%): Ranking of overall costs and cost per sample.

F. Order Response:

G. Technical Proposal shall be 3-4 pages in length and consist of a brief summary of your approach to analytical method implementation, the schedule for sample analysis as batches are received, and the relevant experience with similar tasks and timelines.

The Business Response shall at least include a coversheet and a budget (provided substantially as indicated in Part II of this form). The Coversheet shall at least consist of:

- RFP Number
- Task Order RFP Number
- Name, address, email and telephone number of point of contact
- Name, address, email and telephone number of contract Administration Office (if applicable)
- Date of submission
- Name, title, address, email, telephone and signature of authorized Business Representative (person authorized to sign contracts on behalf of the organization).

There are no Options associated with this Task Order

H. Order Response Due Date: Responses to this Task Order shall be included in your technical and business proposals for this RFP.

TASK ORDER REQUEST FOR PROPOSAL (TORP)

Contractor: _____ [fill in] _____ Contract No: _____

TORFP No: 4 Modification No: 0 Date Prepared: _____

Part II. CONTRACTOR'S RESPONSE TO ORDER REQUEST

(*The Contractor shall attach a detailed budget to this form to identify all proposed fixed- price costs.)

A. Estimated Cost and Effort:

1. Labor hours – list order leader, specific individuals to be assigned, labor category, and estimated hours for each.
2. Labor costs – list by labor category and total.
3. Employee benefits.
4. Direct materials.
5. Travel.
6. Subcontracts.
7. Other direct costs.
8. Indirect costs.
9. Total estimated costs for this Order: _____ *

B. Detailed description of the approach to be used and of the deliverable(s). (Be specific):

APPROVAL TO PROCEED: The Contractor shall not exceed the estimated labor hours, estimated Order amount, or change the Order leader without the prior written approval of the Contracting Officer's Representative and the Contracting Officer.

1. For the Contractor: _____ Date: _____
(Signature)

Typed Name: _____

2. For the Government: _____ Date: _____
Contracting Officer's Representative (COR)

_____ Date: _____
Contracting Officer

TASK ORDER REQUEST FOR PROPOSAL #5

Contractor: _____ TBD _____

Contract No: _____ TBD _____

Pending Order No: #5 Modification No: 0 Order Title: Kick-off Meeting with NCI Staff Task Order Type: Fixed Price (FP)

Order Originator: _____ Date Prepared: _____

NOTE: This Task Order will be funded upon award for each contract resulting from this solicitation**Part I. INITIATOR'S REQUEST**A. Period of Performance: One year from effective date of award.B. Statement of Work/Protocol/Project Description:

The objective of this contract is to acquire for the direct benefit of the Government pharmacological, pharmacokinetic, and ADME data allowing essential characterization of compounds in the NCI drug discovery/development pipeline from early lead optimization to clinical trials. The data will be used to guide candidate selection and possibly be included in an Investigational New Drug application (IND). The Program is seeking Contractors with technical knowledge and capabilities under the ID/IQ mechanism.

Objective: The objectives of this task are:

- Appropriate contractor staff shall participate in a teleconference/webinar with the NCI to discuss the contract workscope.
- NCI staff will explain the ID/IQ contract mechanism and discuss how to respond to Task Order requests and how they are evaluated.
- A review of expectations and results will be given. The Contracting Officer's Representative (COR) will provide an overview of the Program and address expectations and other critical elements of task order assignments.
- Please allow approximately one-half hour for a question and answer period immediately following the presentation by NCI Staff

This meeting will take place using videoconferencing facilities to be provided by the two parties. In the event it is not possible to connect via videoconferencing, a web-based presentation (webinar) will be held. Please include all key personnel in addition to business representatives and staff who will be most involved in contract activities. It is anticipated the duration of this event will be not more than two hours. A formal presentation by the contractor is not required.

C. Deliverables:

- Participation of key contractor staff in an approximately 2-hour videoconference (or webinar) with NCI staff.

D. Additional Instructions:

- Task Orders will normally be competed among the contractors if multiple awards are made pursuant to this RFP. It is anticipated that this initial Task Order will be awarded to all successful offerors at the time of contract award.

E. Evaluation Factors:

Responses will be reviewed based on the following factors, in order of importance:

- Appropriateness of the personnel proposed for participation in the kick-off meeting
- Cost reasonableness

F. Order Response:

The technical response shall contain a listing of the personnel proposed to participate in the kick-off meeting and a brief description of their roles in the project.

The Business Response shall at least include a Coversheet and a Budget (provided substantially as indicated in Part II of this form). The Coversheet shall at least consist of:

- RFP Number
- Task Order RFP Number
- Name, address, email and telephone number of point of contact
- Name, address, email and telephone number of contract Administration Office (if applicable)
- Date of submission
- Name, title, address, email, telephone and signature of authorized Business Representative (person authorized to sign contracts on behalf of the organization).

G. Order Response Due Date:

Responses to this Task Order shall be included in your technical and business proposals for this RFP.

TASK ORDER PROPOSAL RESPONSE

Contractor: TBD Contract No: TBD

Pending Order No: #5 Modification No: 0 Date Prepared: _____

Part II. CONTRACTOR'S RESPONSE TO ORDER REQUEST

(*The Contractor shall attach a detailed budget to this form to identify all proposed fixed-price costs.)

A. Estimated Cost and Effort:

1. Labor hours – list order leader, specific individuals to be assigned, labor category, and estimated hours for each.
2. Labor costs – list by labor category and total.
3. Employee benefits.
4. Direct materials.
5. Travel.c
6. Subcontracts.
7. Other direct costs.
8. Indirect costs.
9. Total estimated costs for this Order: _____ *

B. Detailed description of the approach to be used and of the deliverable(s). (Be specific):

*Note: The cost of this Task Order may not be \$0.00.

APPROVAL TO PROCEED: The Contractor shall not exceed the estimated labor hours, estimated Order amount, or change the Order leader without the prior written approval of the Contracting Officer's Representative and the Contracting Officer.

1. For the Contractor: _____ Date: _____
(Signature)

Typed Name: _____

2. For the Government: _____ Date: _____
Contracting Officer's Representative (COR)

_____ Date: _____
Contracting Officer