

# SOLICITATION

## SECTION A - SOLICITATION/CONTRACT FORM

1. Requisition or other Purchase Authority: <u>42 U.S.C. 285 (j)</u>		
<b>2. Request for Proposal (RFP) Number:</b>  NIH-NINDS-14-01	<b>3. Issue Date:</b> _____  <b>April 9, 2014</b>	<b>4. Set Aside:</b> <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes See Part IV Section L
5. Title : Clinical Support Services for the Clinical and Research Efforts of the NINDS Stroke Branch, Section on Stroke Diagnostics and Therapeutics, NINDS, NIH		
6. ISSUED BY: Office of Acquisitions, Neurosciences NINDS R&D CMB, NIDA National Institutes of Health 6001 Executive Blvd., Suite 3287 Bethesda, MD 20892-9531	7. SUBMIT OFFERS TO:  See Part III, Section J, "Packaging and Delivery of the Proposal," ATTACHMENT 1 of this Solicitation.	
8. Proposals for furnishing the supplies and/or services in THE SCHEDULE will be received at the place specified in, and in the number of copies specified in Attachment 1, "Packaging and Delivery of the Proposal," until 5:00 pm local time on <b>June 9, 2014</b> . Offers will be valid for 120 days unless a different period is specified by the offeror on Attachment No. 6 of Section J entitled, "Proposal Summary and Data Record, NIH 2043.		
9. This solicitation requires delivery of proposals as stated in ATTACHMENT 1, "PACKAGING AND DELIVERY OF THE PROPOSAL." If proposals are required to be delivered to two different locations, the OFFICIAL POINT OF RECEIPT for determining TIMELY DELIVERY is the address provided for the OFFICE OF ACQUISITIONS.  IF YOUR PROPOSAL IS NOT RECEIVED BY THE CONTRACTING OFFICER OR HIS DESIGNEE AT THE PLACE AND TIME SPECIFIED FOR THE OFFICE OF ACQUISITIONS, THEN IT WILL BE CONSIDERED LATE AND HANDLED IN ACCORDANCE WITH subparagraph (c)(3) of FAR Clause 52.215-1, Instructions to Offerors--Competitive Acquisition," LOCATED IN SECTION L.1. OF THIS SOLICITATION.		
10. Offeror must be registered in the Central Contractor Registry (CCR) prior to award of a contract. Offerors must access the CCR through The System for Award Management (SAM) at <a href="http://www.sam.gov">http://www.sam.gov</a>		
11. FOR INFORMATION CALL: Annette Carter PHONE: 301-496-1813 e-MAIL: <a href="mailto:cartera@mail.nih.gov">cartera@mail.nih.gov</a> COLLECT CALLS WILL NOT BE ACCEPTED.		
		Annette Carter Contracting Officer Office of Acquisitions NINDS R&D CMB, NIDA, NIH

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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 proposed contract will provide an acute care hospital setting for NINDS intramural medical staff to access, treat and study acute stroke and TBI patients. The contractor shall provide clinical support services, i.e., nurses and physicians, for triaging and screening patients who present with acute stroke and/or TBI symptoms and will support patient care and intervention activities performed directly by NINDS DIR staff at the Contractor's site.

### ARTICLE B.2. ESTIMATED COST – OPTIONS

- a. The estimated cost to the Government for the base contract period, including all direct and indirect costs is \$ \* **(to be inserted as a result of negotiations)**. In addition to the base contract, the Government will also have the right to exercise four additional one-year term options. The total estimated cost of the contract will be increased by award of future options, if exercised. The award of any option(s) will be made pursuant to the terms and conditions set forth in Article H.6., Option Provisions. The obligations associated with the exercise of an option, if any, will be made pursuant to the terms and conditions of the Limitations of Cost clause made a part of this contract under Section I.
- b. The total estimated amount negotiated for the base contract plus all possible options is as follows:

Contract Line Item Number (CLIN) and Description	Period of Performance	Estimated Cost (\$)
CLIN 1 - Base Contract – Year 01 (12 months)	9/01/2014 - 8/31/2015	*
CLIN 2 - Option No. 1 - Year 02 (12 months)	9/01/2015 - 8/31/2016	*
CLIN 3 - Option No. 2 - Year 03 (12 months)	9/01/2016 - 8/31/2017	*
CLIN 4 - Option No. 3 - Year 04 (12 months)	9/01/2017 - 8/31/2018	*
CLIN 5 - Option No. 4 - Year 05 (12 months)	9/01/2018 – 8/31/2019	*

Costs for the base contract and each 12-month option term will be tracked separately and disbursements will correspond to the 12-month period in which those funds are properly chargeable.

- c. If the Government does NOT intend to exercise a subsequent Term Option as contained in paragraph (b) above, the Contractor will be informed 45 days prior to contract expiration in order to allow for an orderly shutdown of activities. Otherwise, the Government shall notify the contractor in writing at least 30 days in advance of its intent to exercise any subsequent Term Option listed in paragraph (b) above and as addressed in the FAR Clause at 52.217-9, Option to Extend the Term of the Contract, made a part of this contract in Article I.3., ADDITIONAL CONTRACT CLAUSES.

### 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. General Requirements**

The purpose of this contract is to acquire the services of an acute care hospital (hereafter identified as the Contractor) located within 15 miles of the NIH campus in Bethesda, MD (9000 Rockville Pike, Bethesda, MD 20892) to support the clinical and research efforts of the NIH/NINDS Stroke Branch, Section on Stroke Diagnostics and Therapeutics (hereafter identified as NIH Team). The overall program is designed to study the use of Magnetic Resonance Imaging (MRI) in the clinical evaluation of acute stroke and traumatic brain injury (TBI) patients, and to develop acute stroke therapies. Although the Contractor will not be developing or conducting any of the research under this program, they will be providing support and clinical services including but not limited to: patient identification and referral; MRI and CT support for imaging of prospective patients for referral and research subjects; vascular neurology physician services; nurse coordinator services; emergency preparation and blinding of study drugs by a hospital pharmacist; chemistry and hematological laboratory tests required by the NIH Team research protocols and NIH Stroke Care Pathway; general radiological services; neurosurgical and neuroradiological services; interventional radiology services; neurointensive care and monitoring. This contract will only reimburse the services necessary to support the research initiated and conducted by the NIH Team.

#### **B. Mandatory Requirements**

The following mandatory requirements are applicable to this effort:

1. **Location of Contractor:** Contractor must be located within 15 miles of the NIH Campus (9000 Rockville Pike, Bethesda, MD 20892). Since the goal of this program is to evaluate acutely ill patients, the proximity of the hospital to NIH is critical to permit clinical and scientific staff the ability to travel quickly from NIH to Contractor's site to manage the care of these patients.
2. **Certification:** Hospital shall have achieved Primary Stroke Center Certification or Comprehensive Stroke Center Certification by The Joint Commission and, for hospitals in Maryland, the additional certification as Primary Stroke Center by the Maryland Institute for Emergency Medicine Services Systems Stroke (MIEMSS) Designation.

#### **C. Specific Performance Requirements and Commitments**

All elements of the performance requirements and commitments shall be in place and operational at the time of the initiation of the contract.

1. **Elements of Stroke Unit:** The Contractor shall provide beds for patients on the Stroke Service with ICU level and ICU-step with appropriate levels of neuroscience nursing staffing and beds equipped with standard cardiovascular and neurointensive monitoring equipment. Additional equipment specific for the clinical needs for the stroke care may be specified by the NIH Stroke Team.
2. **NIH Stroke Care Pathway:** The NIH Stroke Team has developed and shall implement at the Contractor's site a critical pathway for stroke patient care (NIH Stroke Care Pathway). The pathway is developed using evidence based medicine to standardize clinical (non-experimental) care of stroke patients in order to limit the variability introduced by individual practice styles. This pathway will be modified as needed to reflect changes in the state of knowledge and expert practice in the care of stroke patients. For all modifications, input from the Contractor's departments involved in the care of stroke patients will be welcome and given serious consideration.
3. **Designation as Stroke Service:** The Contractor shall recognize the NIH Stroke Team as the designated in-patient and on-call emergency acute stroke service for the hospital. The clinical structure of the NIH Stroke Service, NIH Stroke Care Pathway, and range of acute cerebrovascular disease to be referred to the NIH Stroke Team and admitted to the NIH Stroke Service (hereafter referred to as Clinical Requirements) will be determined by the NIH Stroke Team. The Clinical Requirements may be revised by the NIH Stroke Team based on clinical and research requirements and the staffing and the nature of the clinical collaborations with

the Contractor's staff. This Clinical Requirements will be communicated to the Contractor's Principal Investigator (PI) and clinical departments. It is understood that the clinical care activities of the NIH Stroke Team will be restricted to the Clinical Requirements and may not involve all patients with acute cerebrovascular disease.

Upon referral of appropriate patients, as specified by the Clinical Requirements, the NIH Stroke Team will take responsibility for emergency evaluation and in-patient management of patients with cerebrovascular disease unless that care is transferred by the NIH Stroke Team to the care of other physicians. The NIH Stroke Team physician will be the attending of record for the patient admitted to the NIH Stroke Service, unless the attending role is declined or transferred to another of the Contractor's staff.

Upon approval of the NIH Team, Contractor staff may participate as clinical members of the NIH Stroke Team in an attending, faculty and/or on-call capacity, on the condition of strict adherence to the NIH Stroke Care Pathway and research protocol requirements. It is understood that NIH Stroke Team will not provide continuous 24 hour "in-hospital" neurologist staffing of the NIH Stroke Service.

Interdepartmental collaboration will be essential to the goals of this contract and enhance patient care and research. The Contractor shall foster and facilitate an adequate and acceptable collaboration between the NIH Team and the other hospital departments, and between the NIH Team and private practice physicians. For any conflict regarding issues of patient care between the NIH Team and other members of the Contractor's Staff that cannot be resolved without the intervention of hospital administration, the Contractor shall commit to the principle that in matters of clinical care of stroke patients priority is given to the authority of the NIH Stroke Team as specified in the NIH Stroke Care Pathway and NIH Stroke Team physician's best clinical judgment. For conflicts over research issues, priority shall be given to the specifics of protocols approved by NIH and the Contractor's IRB committees. Except for emergency or life-threatening situations, no deviation in the care specified by the NIH Stroke Care Pathway or by an approved research protocol shall be instituted (i.e., no orders written) by a physician outside of the Stroke Service without prior discussion and agreement by the responsible clinician on the Stroke Service.

4. **Emergency Services:** The Emergency Department of the Contractor shall refer a minimum of 90% of appropriate acute stroke admissions (as designated in the Clinical Requirements) to the NIH Stroke Team for evaluation. The Contractor shall assign one nurse at all times as primarily responsible to support in the initial clinical evaluation and management of acute stroke patients according to the NIH Stroke Care Pathway, recording of data, and monitoring patients who leave the emergency department for diagnostic procedures. The cost associated with such support is the responsibility of the Contractor. See Section C.18 - Division of Cost Responsibility.

The Emergency Department of the Contractor shall facilitate the referral of traumatic brain injury patients for possible enrollment into the traumatic brain injury research protocols.

5. **Patient Referral:** Upon identification of appropriate patients specified in the NIH Stroke Care Pathway according to Clinical Requirements, emergency room staff (or in-patient unit staff in the case of strokes occurring in hospital) shall promptly page the on-call NIH Stroke Team to evaluate the patient for treatment and/or recruitment into a research protocol. The ability of the hospital to meet the 90% patient referral standard will be reviewed quarterly. The NIH Stroke Team shall be provided with access to patient demographic and admission information to determine whether compliance with the referral rate is being met. Inadequate referral activity that jeopardizes the success of the NIH research protocols may preclude the Government from exercising any future options under the contract.
6. **Support Staff and Ancillary Services:** Other hospital-based services shall be provided to support standard stroke care and are essential elements of the established NIH Stroke Care Pathway. These include, but are not limited to, nursing, neurosurgery, interventional neuroradiology, speech therapy, occupational therapy, and physical therapy. The cost associated with such support is the responsibility of the Contractor. See Section C.18 - Division of Cost Responsibility.
7. **MRI Facility and Equipment:** A major research focus of this program is the use of MRI in the evaluation and investigation of stroke and traumatic brain injury patients. Thus, a state-of-the-art MRI scanner (1.5T or 3T) and facility is critical for the program's needs.

- a. Patient Preparation Area - This area shall be used to prepare, examine, and interview patients. The room shall be capable of patient exams, minor procedures and general patient preparation.
- b. Patient Treatment Area - This area shall be used to monitor or treat patients with standard or experimental therapies while within the MRI facility. Cardiovascular monitoring equipment and emergency resuscitation equipment ('crash cart') will be available in this area. This area will be stocked with sufficient supplies of medications required by the NIH Team. A nurse will be available whenever needed to assist in monitoring patients undergoing studies in the MRI facility.
- c. MRI Facility Location - The state-of-the art MRI scanner shall be located near the Emergency Department such that patient transport from the Emergency Department to the MRI facility can readily and routinely be accomplished in less than 5 minutes. The scanner shall be available 24/7 for use in the evaluation of acute stroke and traumatic brain injury patients. Proximity to the Stroke Unit, CCU or other critical patient monitoring areas is desirable. Access to the state-of-the art MRI scanner by NIH Team shall include scheduled research time during normal operating hours, and additional hours may be scheduled for other times. Normal operating hours are defined as Monday through Friday 8am through 7pm. The scanner shall be immediately accessible at all times for emergency evaluation of stroke patients (no greater than 15 minute delay between notification of technologist of emergency stroke case and scanner readiness for the patient). Access to the MRI scanner by the NIH Team for emergency, clinical follow-up, or research scans, will not require approval by the Contractor's radiologist or other staff. Outside of normal operating hours, the scanner shall be available for NIH Team stroke clinical scans and research studies. Use of the MRI scanner by the NIH Team may not be limited in any manner by the Contractor.
- d. Scanner Upgrades - Contractor shall be responsible for coordinating and implementing required scanner upgrades as necessary. The NIH Team shall be kept informed of any contemplated maintenance, changes, or upgrades to the MRI system. No changes shall take place without the input and agreement of the NIH Team. Payment of upgrade and maintenance costs with the use of contract funds will be determined on a case-by-case basis.

8. **Radiology Services:** In addition to MRI unit, the Contractor shall provide 24 hour access for clinical scanning of stroke patients in a state-of-the-art CT scanner for stroke patients including capacity for CT angiography and CT perfusion.

Clinical stroke imaging protocols will be determined through collaboration and mutual agreement between the NIH Team and the Contractor's radiologists.

The Contractor shall make available 24 hour interventional neuroradiologist coverage with emergency on-call neuroradiological services for image interpretation or interventional procedures. The requirement for interventional procedures will always be available for emergency diagnostic angiography and intra-arterial thrombolysis of cerebral arteries and other endovascular therapies and research collaborations. Contractor's neuroradiologists shall provide stat reads of emergency CT scans and MRI scans. The neuroradiological services may also, at the NIH Team's designation, be provided by NIH personnel in addition to the Contractor's personnel, and the contractor would not limit granting of clinical privileges or access to required hospital resources to such designees without just cause.

9. **Medical Staff Privileges and Billing:** Upon request and following standard application and review, the Contractor shall grant clinical privileges to NIH personnel to perform clinical services and procedures for which they have adequate training and experience in support of the clinical and research needs of the NIH Team. Such privileges and/or access to required hospital resources shall not be denied for reasons of competition with other Contractor's staff or clinical services for any reasons other than professional competency. NIH employed physicians will not charge or bill for their clinical services and the Contractor may not bill for NIH employed physicians either directly or indirectly. The Contractor shall not hire for employment any member of the NIH Team while that member is an NIH employee or within 1 year of termination of NIH employment, without prior permission of the NIH team.
10. **Training:** The NIH Stroke Program has an Accreditation Council for Graduate Medical Education (ACGME) vascular neurology residency program. The Contractor shall agree to enter into a Program Letter of Agreement with NIH to allow the NIH vascular neurology residents to do inpatient and outpatient rotations at

the Contractor's site. The Contractor shall provide vascular neurologist(s), at least one of whom shall be American Board of Psychiatry and Neurology (ABPN) Board Certified in Vascular Neurology, to serve as faculty for this training program and to assist with the education and training of the NIH vascular neurology residents during their inpatient and outpatient rotations. Contractor shall provide sufficient resources (faculty, space and other ancillary support) to ensure the outpatient rotation provides valuable teaching experience for the NIH vascular neurology residents.

11. **Community Outreach:** The hospital shall provide, at no cost to the Government, community outreach services to educate the potential patient population in the Contractor's community about stroke prevention and treatment, about the NIH clinical care and research programs and to foster a receptive attitude toward participation in NIH research studies.
12. **In-service Training:** The NIH Team shall be responsible for training Contractor's clinical staff members in the NIH Stroke Care Pathway and research protocol requirements. Sufficient time and access to the Contractor's clinical staff to provide education and training in regard to research protocols shall be provided.
13. **Non-transfer of Acute Patients:** The Contractor shall seek designation with the various HMO plans to be recognized as an acute stroke center for that provider. This will help reduce the number of patients who are transferred from the Contractor's emergency room or within 24 hours of admission to another hospital because of insurance membership constraints.
14. **Patient follow-up after hospital discharge:** Patients seen by the NIH Team will be referred to an appropriate physician for follow-up (non-research related) care. The NIH Team will need to maintain contact with the patient once they are enrolled in a research protocol and will contact or see patients in follow-up for the purpose and according to the requirements of the research protocols.
15. **Research Pharmacist Availability:** It is anticipated that drug treatment research protocols will require emergency preparation and blinding of study material (drug or placebo) by a pharmacist. Thus, during the activity of such protocols, a pharmacist must be available at all times in hospital (24/7) to perform the functions required by the protocol on an emergency basis. Only actual effort associated with preparing study materials or providing research pharmacy services as related to implementation of research protocols shall be an allowable cost to the contract.
16. **Diagnostic Tests/Supplies/Services:** The majority of diagnostic tests shall be performed as part of clinical services and thus not reimbursable cost under this contract. It is anticipated that research protocols may require chemistry or hematological laboratory tests to be performed and reported urgently (stat) that may not typically be considered stat. Thus, the laboratory shall make available the resources to perform the tests required by the research protocols and in a manner required by the protocols. The Contractor shall provide these tests as required by the research protocols. The costs for any diagnostic tests related to the research protocols shall be allowable costs under this contract. The NIH Stroke Team may elect to send their research laboratory tests to an outside facility for processing.
17. **Costs of patient transfer from another facility:** The cost of transferring a patient by air or land from another facility to the Contractor's hospital may not be passed on to the Government unless the primary reason for the transfer is participation in an approved research protocol of the NIH Team and the research participation was initiated (e.g., informed consent obtained) prior to the transfer.
18. **Division of Cost Responsibility:** The cost requirements of the program that are of clinical necessity (e.g., routine clinical care, NIH Stroke Care Pathway, maintenance of stroke center certification) shall be the responsibility of the Contractor.

Any cost to establish and maintain emergency and inpatient clinical, laboratory, and radiological services as specified by the NIH Stroke Care Pathway shall be the responsibility of the Contractor. This will include any costs of upgrading or expanding human or equipment resources not currently available or sufficient to meet the needs of the care of stroke patients.

The cost of those elements required by the research protocols of the program shall be the responsibility of the Government and shall be allowable costs under this contract.

Note, if a patient's insurance company declines to pay for a clinical service the cost of that service will not be reimbursed under this contract.

19. **Research Costs:** Research patient care costs shall be reimbursed by this contract in accordance with, if applicable, the Contractor's HHS negotiated research patient care rate agreement. In absence of such agreement the research patient care costs will be reimbursed by this contract at the Medicare reimbursement rate.
20. **IRB Approval:** All research performed by the NIH Team shall be reviewed and approved according to IRB requirements for NIH and the Contractor.

The HHSAR Clause at 352.270-4, Protection of Human Subjects, shall be made a part of any contract resulting from this solicitation. However, it is recognized that due to the fact that the Government, and not the Contractor, will be defining, determining and directing any and all activities involving the use of human subjects under the contract, certain terms of the second paragraph of the clause alluded above, specifically the first two sentences, are inconsistent with the actual respective roles and responsibilities of the Government and the Contractor involving human subjects under the contract. Due to these inconsistencies, the following performance terms take precedence over the terms stated in the first two sentences of this paragraph as follows:

"The Contractor shall bear full responsibility for the performance of all work and services involving the use of human subjects as required by the terms of the contract Statement of Work and as required by the NIH Stroke Team in performance of the research protocols and NIH Stroke Pathway, and shall ensure that their work is conducted in a proper manner and as safely as possible. The parties agree that the Government retains the right to control and specify the performance of all work under this contract."

In addition, it is understood and agreed that the NINDS is sponsoring and conducting research activities involving human subjects under this contract via implementation of specific research protocols. The Contractor however shall be responsible for providing evidence of their IRB's, or reliance on NIH's IRB review and approval, of all project activities involving human subjects. Contractor staff will not be responsible for any analysis or interpretation of research results. The Contractor shall be responsible for referral of patients, standard/routine care, evaluation and treatment of subjects referred to and enrolled under the NIH Stroke Team protocols and all other patient activities as may be directed by the NIH Stroke Team or required by the Stroke Pathway.

The Contractor shall be required to establish and maintain a federal-wide assurance (FWA) approved by the HHS Office for Human Research Protections (OHRP) or establish an agreement with OHRP to recognize the authority of the NIH IRB, for themselves and any subcontractor, or cooperating institution having responsibility for human subjects involved in performance of a contract. OHRP is responsible for negotiating assurances covering all HHS-supported or HHS-conducted activities involving human subjects

Contractor shall provide, on an annual basis, acceptable assurance that all work conducted under the contract will be reviewed by an appropriate Institutional Review Board (IRB) as described in HHS regulations at [45 CFR 46.103](#).

Institutions having an OHRP-approved FWA shall provide evidence of IRB approval of submitted proposals in the manner required by instructions for completion of the contract proposal; by completion of an [OMB Form No. 0990-0263](#), "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption (Common Rule); or by letter indicating the institution's OHRP-assigned FWA number, the date of IRB review and approval, and the type of review (convened or expedited). The date of IRB approval must not be more than 12 months prior to the deadline for proposal submission.

The HHSAR clause at [352.270-6, Restriction on Use of Human Subjects](#), shall also be included in any resultant contract if the contractor selected for award has an approved federal-wide assurance of compliance in place, but cannot certify prior to award that any of the human subject activities or research protocols have been reviewed and approved by the IRB designated under their federal-wide assurance of compliance, because definite plans for involvement of human subjects are not known or set forth in the proposal (e.g., projects in which human subjects' involvement will depend upon the Contractor being made privy to the ongoing specific NIH Stroke Team research protocols). Under these conditions, the Contracting Officer may

make the award without the requisite certification, as long as the Contracting Officer includes appropriate conditions in the contract.

21. **Computer Networks:** The Contractor shall allow and facilitate the NIH network to be installed at their hospital site. The Contractor's CT scanners and MRI scanners shall be made accessible to NIH computer network. All NIH Team office facilities at the Contractor's site shall require high speed computer links with the NIH's and Contractor's computer networks.
22. **Proprietary Research Data:** The resulting research data collected shall be proprietary to NIH Team except for medical necessity. Any use of the research data collected by the NIH Team cannot be used by non-NIH personnel for scientific, academic, educational, commercial or other purposes without the permission of the NIH Team and in accordance with NIH policy.
23. **Space Requirements:** Adequate office space and office furnishings for 8-10 members of the NIH Team shall be provided on hospital premises by the Contractor. This space shall be in proximity to the MRI facility and the Stroke Unit. During the course of the contract period the clinical and research activities and staffing of the program may grow. If space requirements of the NIH Program increase, sufficient and acceptable space and furnishings shall be made available to the NIH Team. If the Contractor requires relocation of the NIH Team offices, the costs of relocation and renovation to a comparable space shall be the responsibility of Contractor. This office space shall be computer network accessible to both the Contractor's and NIH's computer networks.
24. **Clinical Research Infrastructure:** The Contractor shall provide the clinical infrastructure to support the research and clinical protocols of the NIH Team as discussed in the general and specific requirements of this statement of work. In addition, the Contractor shall provide medical records support to insure that copies of consents generated by the NIH Team are incorporated into the appropriate hospital medical records.
25. **Reporting Requirements:** The Contractor shall prepare and deliver written quarterly technical progress reports on the numbers and types of patients referred to the NIH Team. These reports shall be electronically delivered to the Contracting Officer (CO) and Contracting Officer Representative (COR).

Delivery of electronic versions of reports shall comply with Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998. Pursuant to Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998, all electronic and information technology (EIT) products and services developed, acquired, maintained, and/or used under this contract 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. All reports that are delivered electronically (e.g., via e-mail) must meet the requirements of Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d). Section 508 governs electronic information viewable at <http://www.section508.gov> and requires that:

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

Additional information about testing documents for Section 508 compliance, including specific checklists, by application, can be found at: <http://www.hhs.gov/web/508/index.html> under "Helpful Resources."

26. **Publicizing Relationship:** The Contractor shall get prior written approval from Contracting Officer to publicize, or to use for marketing purposes, their relationship or association with NIH/NINDS.
27. **Program Management and Control Requirements:** The Contractor shall appoint either a senior administrator or Stroke Center Medical Director as Principal Investigator (PI) to serve as a liaison between the NIH Team, Contractor's corporate management and clinical support staff. In addition, if NIH Team deems necessary, monthly meetings shall occur between the PI and NIH staff to assure referral of patients, contract compliance and support of the NIH clinical and research protocols.

**D. Clinical Support – Roles and Responsibilities:**

1. **Stroke Center Medical Director:** The Contractor shall have a Stroke Center Medical Director. The Director shall help facilitate the clinical and research activities of the NIH Team and assist with the education and training of NIH vascular neurology residents. This position will serve as a liaison between the NINDS COR and the Contractor's staff. Support of this position based on level of effort will be an allowable cost under this contract.
2. **Clinical Support Services:**
  - a. At least one member of the hospital's stroke center medical staff shall be ABPN board certified in vascular neurology. Additional vascular neurology faculty to provide support of clinical research activities and education and training of residents is not required but will be considered if proposed.
  - b. The contractor shall provide contract dedicated, full-time nurse coordinator to work with the NIH Team in support of the NIH research activities. Support of this position will be an allowable cost under this contract. Offeror must address timeline and methods to recruit staff for this position if not already existing.
  - c. The contractor shall provide 24/7 MRI technologist support for the MRI scanner facility. The Contractor and the NIH Team shall jointly designate one MRI technologist to serve as liaison between the NIH Team and the Contractor's MRI technologist staff to optimize communication and compliance with the technical requirements of scanning protocols. The MRI technologists may be utilized to scan routine clinical (i.e., non-research, non-NIH Team) patients when not required for NIH Team scans. The NIH Team shall be given a daily MRI schedule of patients and the technologists on duty if required. The Contractor shall maintain standard procedures for training and documenting the competency of MRI technicians in stroke imaging protocols, changes in imaging protocols or addition of new imaging protocols. NIH reserves the right to provide input regarding the performance of each technologist. The Contractor shall propose how they will provide this support
  - d. The Contractor shall provide administrative support services to the NIH Team. Only services in direct support of the NIH Team's activities will be considered as an allowable cost under this contract and must be justified.
  - e. Research Pharmacist – See Section C.1. paragraph (15) above.

**ARTICLE C.2. REPORTING REQUIREMENTS/DELIVERABLES**

All reports required herein shall be delivered in electronic format. In addition, one (1) hardcopy of each report shall be delivered to the CO, unless otherwise specified.

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

All paper/hardcopy documents/reports delivered 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).

The Contractor shall prepare and deliver the following reports in the manner stated below and in accordance with the DELIVERIES Article in SECTION F of this contract. These report deliverables are applicable to the base contract and each exercised option period.

1. **Quarterly Technical Progress Reports** – These reports shall briefly summarize the work performed and specify the numbers and types of patients referred to the NIH Team for each month of the reporting period.
2. **Information Security and Physical Access Reporting Requirements** – The Contractor shall submit the following reports as required by the Information and Physical Access Security Article in Section H of this contract.

- a. Roster of Employees Requiring Suitability Investigations** - The Contractor shall submit a roster, by name, position, e-mail address, phone number and responsibility, of all staff (including subcontractor staff) working under the contract who will develop, have the ability to access, or host and/or maintain a Federal information system(s). The roster shall be submitted to the Contracting Officer's Technical Representative (COTR), with a copy to the Contracting Officer, within 14 calendar days of the effective date of the contract.
- b. Reporting of New and Departing Employees** - The Contractor shall notify the Contracting Officer's Technical Representative (COTR) and Contracting Officer within five working days of staffing changes for positions that require suitability determinations as follows:
- 1) **New Employees who have or will have access to HHS Information systems or data:** Provide the name, position title, e-mail address, and phone number of the new employee. Provide the name, position title and suitability level held by the former incumbent. If the employee is filling a new position, provide a description of the position and the Government will determine the appropriate security level.
  - 2) **Departing Employees:** 1) Provide the name, position title, and security clearance level held by or pending for the individual; and 2) Perform and document the actions identified in the "Employee Separation Checklist", attached in Section J, ATTACHMENTS of this contract, when a Contractor/Subcontractor employee terminates work under this contract. All documentation shall be made available to the COTR and/or Contracting Officer upon request.
- c. Contractor - Employee Non-Disclosure Agreement(s)** - The contractor shall complete and submit a signed and witnessed "Commitment to Protect Non-Public Information - Contractor Agreement" form for each contractor and subcontractor employee who may have access to non-public Department information under this contract. This form is located at: <http://ocio.nih.gov/docs/public/Nondisclosure.pdf>

**(For paragraphs 2. (a), (b), and (c), above, refer to Article H.8 - INFORMATION AND PHYSICAL ACCESS SECURITY, subparagraph D.2. of this contract.)**

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

### ARTICLE C.3. INVENTION REPORTING REQUIREMENT

All reports and documentation required by FAR Clause 52.227-11, Patent Rights-Ownership by the Contractor FAR Clause 52.227-13, Patent Rights-Ownership by the Government 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.

As required by the terms of the above cited clause, the Contractor shall also deliver to the Contracting Officer, at the address stated below, both annual invention utilization reports and a "final invention statement and certification" report. The annual invention utilization reports shall list any and all inventions required to be disclosed during the 12-month period covered by the annual report. The final invention report shall list any and all subject inventions required to be disclosed covering the entire contract period. For both the annual and final invention reports, 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 delivered. The Contractor may use the attached form HHS 568 entitled "Final Invention Statement and Certification" for both the annual and final invention reports. If no inventions were involved, insert the word "None" in the first block under the item "Title of Invention" on the 568 form.

Contracting Officer  
National Institutes of Health  
Office of Acquisitions, Neurosciences

NINDS R&D CMB, NIDA  
6001 Executive Blvd., Room 3287  
Bethesda, Maryland 20892-9531

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

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

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

### **ARTICLE D.1. PACKAGING**

For the purpose of reports, "immediately usable and acceptable condition" includes securing the pages together in a suitable and reasonable manner to be agreed upon by the Contracting Officer (CO) and the NINDS Contracting Officer Representative (COR).

Boxes and/or other types of outer packaging, i.e., containers, wraps, etc., shall be suitable to the type of items being transmitted; and the mode of transportation utilized shall assure that such materials be received in an acceptable condition.

### **ARTICLE D.2. MARKING**

All reports/deliverable items under this contract shall be marked on the cover and cover page with the following identifiers.

1. Project Title: "Clinical Support Services for the Clinical and Research Efforts of the NINDS Stroke Branch, Section on Stroke Diagnostics and Therapeutics, NINDS, NIH"
2. Contract Number:
3. Name of Contractor:
4. Name of Stroke Center Medical Director (Principal Investigator):

### **ARTICLE D.3. SHIPPING**

Shipping shall be accomplished by reasonable and suitable means to be mutually agreed upon by the Contractor and the NINDS COR.

See Section F for delivery information.

**SECTION E - INSPECTION AND ACCEPTANCE**

- a. The CO or the duly authorized representative shall perform inspection and acceptance of materials and services to be provided.
- b. For the purpose of this Article, the NINDS COR identified in Article. G.1. is an authorized representative of the CO.
- c. Inspection and acceptance of contract work, services, and/or deliverables shall be performed at the National Institute of Neurological Disorders and Stroke (NINDS), NIH **(to be completed after negotiations)** or at the Contractor's facility. Site visits may also be employed for the purposes of monitoring progress of work. Acceptance of work and/or report deliverables may be presumed unless otherwise indicated in writing by the CO 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 CO will make its full text available.

**Federal Acquisition Regulation 48 CFR Chapter 1) Clause:**

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

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

- a. The period of performance of the base contract shall be from 09/01/2014 through 08/31/2015.
- b. If the Government exercises its options pursuant to Article H.6., OPTION PROVISIONS of this contract, the period of performance will be extended as indicated below:

<b>Option</b>	<b>Period of Performance</b>
CLIN 2 - Option No. 1 - Year 02 (12 months)	09/01/15 - 08/31/16
CLIN 3 - Option No. 2 - Year 03 (12 months)	09/01/16 - 08/31/17
CLIN 4 - Option No. 3 - Year 04 (12 months)	09/01/17 - 08/31/18
CLIN 5 - Option No. 4 - Year 05 (12 months)	09/01/18 - 08/31/19

**ARTICLE F.2. DELIVERIES**

The items specified below, and as described in Articles C.2., C.3 and H.7 shall be delivered F.o.b. Destination as set forth in FAR Clause 52.247-35, F.o.b. DESTINATION, WITHIN CONSIGNEES PREMISES (APRIL 1984), hereby made a part of this contract, and in accordance with and by the dates specified below:

<b>Article C.2 Item #</b>	<b>Description</b>	<b>Quantity</b>	<b>Due Date</b>
1	Quarterly Technical Progress Report	1 e-copy to the CO and COR	Three months from contract award date and quarterly thereafter.
2 a.	Roster of Employees Requiring Suitability Investigations	1 e-copy to the CO and COR	14 days after effective date of contract and on the 5 <sup>th</sup> day of each month thereafter.
2 b.	Reporting of New and Departing Employees	1 e-copy to the CO and COR	Within 5 days of staffing changes
2 c.	Contractor-Employee Non-Disclosure Agreement(s)	1 e-copy to the CO and COR	Within 30 calendar days of contract effective date and as applicable thereafter.
3	Section 508 Annual Report	1 e-copy to the CO and COR	On or before the completion date of each reporting period.
<b>Article C.3</b>	Annual Invention Utilization Report	1 e-copy to the CO	On or before the completion date of each reporting period.
<b>Article C.3</b>	Final Invention Statement and Certification	1 e-copy to the CO	On or before the expiration/termination date of the contract.
<b>Article H.7</b>	Individual Subcontract Report (ISR)	Electronic Submission	April 30 <sup>th</sup> and October 30 <sup>th</sup> of each Period of Performance
<b>Article H.7</b>	Summary Subcontract Report (SSR)	Electronic Submission	October 30 <sup>th</sup> of each Period of Performance

All electronic reports submitted shall be compliant with Section 508 of the Rehabilitation Act of 1973. See Article C.2., subparagraph (e), and Article H.9.

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).

The e-mail and mailing addresses for the Contracting Officer and Contracting Officer Representative (COR) are as follows:

Contracting Officers:

Annette Carter or Laurie Leonard  
 NINDS R&D CMB, NIDA, NIH  
 6001 Executive Blvd., Room 3287  
 Bethesda, Maryland 20892-9531  
 (FedEx/courier use: Rockville, MD 20852)  
 Email:

COR:

(To be Named)

**ARTICLE F.3. LEVEL OF EFFORT**

- a. In accomplishing the work set forth herein, the Contractor shall provide the direct labor commitment **(to be negotiated)** as indicated below for the base contract year and each option year. The labor commitment does include time-off absences for vacation, holiday, and sick leave. It is estimated that the direct labor commitment for this contract will be expended approximately as follows:

Possible Labor Categories	Percent of Effort/Labor Hours (to be determined*)				
	Base Year of Contract	Option Year 1	Option Year 2	Option Year 3	Option Year 4
Stroke Medical Director/PI					
Stroke Physician					
Nurse Coordinator					
Nurse Practitioner					
MRI Technologist					
Pharmacist					
Administrative Assistant					

\* The offeror shall itemize and provide the required labor mix and/or categories, with their respective levels of effort that are necessary to implement all aspects of the work as outlined in the Statement of Work. The Government realizes that labor mix and respective levels of effort may vary between offerors depending on their organizational structure and approach to provide the requisite services. Offerors must read section "D" of the Statement of Work entitled Clinical Support - Roles and Responsibilities and provide their estimates accordingly.

- b. The Contractor shall have satisfied the requirement for this contract if not less than 90% of the total direct labor effort specified herein is furnished.

**ARTICLE F.4. 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.

**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 NAMED)**

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 alternate COR is responsible for carrying out the duties of the COR only in the event that the COR can no longer perform his/her duties as assigned.]

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 352.242-70 (January 2006)**

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

(End of Clause)

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

Name	Title
	Stroke Center Medical Director (Principal Investigator)

**ARTICLE G.3. INVOICE SUBMISSION/CONTRACT FINANCING REQUEST AND CONTRACT FINANCIAL REPORT**

- a. Invoice Submission/Contract Financing Request and Contract Financial Reporting, NIH(RC)-4for 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.

(A) Payment requests (contract financing requests) shall be submitted to the offices identified below. Submit supporting documentation (e.g., receipts, time sheets, vendor invoices, etc.) with your payment requests as specified below.

(a) An original hard copy invoice (contract financing request), less supporting documentation, 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 electronic copy of the invoice (contract financing request), including ALL supporting documentation, shall be submitted to the following approving official:

Contracting Officer  
NINDS R&D Contracts Management Branch, NIDA  
E-mail: To be determined.

NOTE: Despite sending an electronic copy to the Contracting Officer, the original payment request must still be submitted in hard copy and mailed to the designated billing office (NIH Office of Financial Management) to meet the requirements of a "proper invoice" in order to be paid.

(B) In addition to the requirements specified in FAR 32.905 for a proper invoice/contract financing request, 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:

**Office of Acquisitions, Neurosciences (OAN).**

b) Central Point of Distribution. For the purpose of this contract, the Central Point of Distribution is: **NIDA Invoices NINDS CMB.**

c) Federal Taxpayer Identification Number (TIN). If the Contractor does not have a valid TIN, it shall identify the Vendor Identification Number (VIN) on the payment request. The VIN is the number that appears after the Contractor's name on the face page of the contract. If the Contractor has neither a TIN, DUNS, or VIN, contact the Contracting Officer.

d) DUNS or DUNS+4 Number. The DUNS number must identify the Contractor's name and address exactly as stated in the contract and as registered in the Central Contractor Registration (CCR) database. If the Contractor does not have a valid DUNS number, it shall identify the Vendor Identification Number (VIN) on the payment request. The VIN is the number that appears after the Contractor's name on the face page of the contract. If the Contractor has neither a TIN, DUNS, or VIN, contact the Contracting Officer.

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

f) Unique Invoice/contract financing request Number. Each payment request must be identified by a unique number, which can only be used one time regardless of the number of contracts or orders held by an organization.

g) Contract Title: **"Support Services for the Clinical and Research Effort of the NINDS Stroke Branch, Section on Stroke Diagnostics and Therapeutics, NINDS, NIH."**

h) Contract Period of Performance and/or Line Item: 09/01/14 - 08/31/15 - CLIN 1

- b. Inquiries regarding payment of invoices shall be directed to the designated billing office, (301) 496-6088.
- c. The Contractor shall include the following certification on every invoice for reimbursable costs incurred with Fiscal Year funds subject to the HHSAR Clause 352.231-70, SALARY RATE LIMITATION in SECTION I of this contract. For billing purposes, certified invoices are required for the billing period during which the applicable Fiscal Year funds were initially charged through the final billing period utilizing the applicable Fiscal Year funds:

**"I hereby certify that the salaries charged in this invoice are in compliance with the HHSAR Clause 352.231-70, SALARY RATE LIMITATION in SECTION I of this contract."**

- d. The Contractor agrees to provide with each monthly contract financing request a detailed breakdown of the direct labor/personnel charges claimed, to include: (1) a list of individuals by name; (2) their title/position under the contract; (3) their hourly/annual salary rate; (4) hours or percent of effort charged; and (5) amount claimed for each. In addition, each monthly financing request shall cite the approved DHHS Fringe Benefit and Indirect Cost rate applicable for that billing period and the appropriate base.
- e. Monthly contract financing requests must include the cumulative total expense to date and adjusted (as applicable) to show any amounts suspended by the Government.
- f. The Contractor shall track, record, and report (invoice) costs incurred separately for the base award period and for each subsequent option term that may be awarded under the contract. The monthly contract financing requests submitted under this contract must reflect costs separately for the base contract award and each awarded term option.

**ARTICLE G.4. 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.5. INDIRECT COST RATES**

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

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

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

**ARTICLE G.6. GOVERNMENT PROPERTY**

If this RFP will result in the acquisition or use of Government Property provided by the contracting agency or if the Contracting Officer authorizes in the preaward negotiation process, the acquisition of property (other than real property), this ARTICLE will include applicable provisions and incorporate the HHS Publication, entitled, "HHS Contracting Guide for Contract of Government Property," which can be found at:

[http://www.hhs.gov/hhsmanuals/logisticsmanual/Appendix Q\\_HHS Contracting Guide.pdf](http://www.hhs.gov/hhsmanuals/logisticsmanual/Appendix Q_HHS Contracting Guide.pdf).

**Government Furnished Property - Schedule II-B**

Pursuant to the clause, GOVERNMENT PROPERTY, which will be incorporated and made part of any contract resulting from this solicitation, the Contractor will be furnished some or all of the property listed below for use in direct performance of the contract:

- One (1) each - Dell Computer, NIH Property Tag No.1884133
- One (1) each - Dell Computer, NIH Property Tag No.1807495
- One (1) each - Dell Computer, NIH Property Tag No.01884254
- One (1) each - NEC MultiSync LCD (Computer Monitor), NIH Property Tag No. 01562258
- One (1) each - Dell Laptop Computer, Latitude D620, NIH Property Tag No. 01884133
- One (1) each - HP Laser Jet 1300n Printer, NIH Property Tag No. 01562246

**ARTICLE G.7. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE****a. Contractor Performance Evaluations**

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

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. PROTECTION OF HUMAN SUBJECTS, HHSAR 352.270-4(b) (January 2006)**

- a. The Contractor agrees that the rights and welfare of human subjects involved in research under this contract shall be protected in accordance with 45 CFR Part 46 and with the Contractor's current Assurance of Compliance on file with the Office for Human Research Protections (OHRP), Department of Health and Human Services. The Contractor further agrees to provide certification at least annually that the Institutional Review Board has reviewed and approved the procedures, which involve human subjects in accordance with 45 CFR Part 46 and the Assurance of Compliance.
- b. The Contractor shall bear full responsibility for the performance of all work and services involving the use of human subjects under this contract and shall ensure that work is conducted in a proper manner and as safely as is feasible. The parties hereto agree that the Contractor retains the right to control and direct the performance of all work under this contract. The Contractor shall not deem anything in this contract to constitute the Contractor or any subcontractor, agent or employee of the Contractor, or any other person, organization, institution, or group of any kind whatsoever, as the agent or employee of the Government. The Contractor agrees that it has entered into this contract and will discharge its obligations, duties, and undertakings and the work pursuant thereto, whether requiring professional judgment or otherwise, as an independent contractor without imputing liability on the part of the Government for the acts of the Contractor or its employees.
- c. If at any time during the performance of this contract, the Contracting Officer determines, in consultation with OHRP that the Contractor is not in compliance with any of the requirements and/or standards stated in paragraphs (a) and (b) 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. The Contracting Officer may communicate the notice of suspension by telephone with confirmation 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, after consultation with OHRP, terminate this contract in whole or in part, and the Contractor's name may be removed from the list of those contractors with approved Human Subject Assurances.

(End of clause)

### **ARTICLE H.2. REQUIRED EDUCATION IN THE PROTECTION OF HUMAN RESEARCH PARTICIPANTS**

NIH policy requires education on the protection of human subject participants for all investigators receiving NIH contract awards for research involving human subjects. For a complete description of the NIH Policy announcement on required education in the protection of human subject participants, the Contractor should access the [NIH Guide for Grants and Contracts Announcement](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00039.html) dated June 5, 2000 at the following website:

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00039.html>.

The information below is a summary of the NIH Policy Announcement:

The Contractor shall maintain the following information: (1) a list of the names and titles of the principal investigator and any other individuals working under the contract who are responsible for the design and/or conduct of the research; (2) the title of the education program(s) in the protection of human subjects that has been completed for each named personnel and; (3) a one sentence description of the educational program(s) listed in (2) above. This requirement extends to investigators and all individuals responsible for the design and/or conduct of the research who are working as subcontractors or consultants under the contract.

Prior to any substitution of the Principal Investigator or any other individuals responsible for the design and/or conduct of the research under the contract, the Contractor shall provide the following written information to the Contracting Officer: the title of the education program and a one sentence description of the program that has been completed by the replacement.

**ARTICLE H.3. 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.4. 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.5. RESTRICTION ON ABORTIONS**

The Contractor shall not use contract funds for any abortion.

**ARTICLE H.6. OPTION PROVISION**

Unless the Government exercises its option pursuant to the Option Clause set forth in SECTION I.3., 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 52.217-9, Option to Extend Term of the Contract, set forth in SECTION I.3. of this contract, the Government may, by unilateral contract modification, require the Contractor to provide effort during the additional option terms as defined and set forth in Sections C and F of the contract. If the Government exercises these options, notice must be given at least 30 days prior to the expiration date of this contract. The estimated cost of the contract will also be increased as set forth in Article B.2., paragraph (b) of this contract.

**ARTICLE H.7. SUBCONTRACTING PROVISIONS****a. Small Business Subcontracting Plan**

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

**b. Subcontracting Reports**

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

**1. Individual Subcontract Reports (ISR)**

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

April 30th  
 October 30th  
 Expiration Date of Contract

**2. Summary Subcontract Report (SSR)**

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

October 30th

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

\_\_\_\_\_  
Contracting Officer

## ARTICLE H.8. INFORMATION AND PHYSICAL ACCESS SECURITY

### A. HHS-Controlled Facilities and Information Systems Security

- a. To perform the work specified herein, Contractor personnel are expected to have routine (1) physical access to an HHS-controlled facility; (2) physical access to an HHS-controlled information system; (3) access to sensitive HHS data or information, whether in an HHS-controlled information system or in hard copy; or (4) any combination of circumstances (1) through (3).
- b. To gain routine physical access to an HHS-controlled information system, and/or access to sensitive data or information, the Contractor and its employees shall comply with Homeland Security Presidential Directive (HSPD)-12, Policy for a Common Identification Standard for Federal Employees and Contractors; Office of Management and Budget Memorandum (M-05-24); and Federal Information Processing Standards Publication (FIPS PUB) Number 201; and with the personal identity verification and investigations procedures contained in the following documents:
  1. HHS-OCIO Information Systems Security and Privacy Policy ( <http://www.hhs.gov/ocio/policy/#Security>)
  2. HHS HSPD-12 Policy Document, v. 2.0 ( <http://www.whitehouse.gov/sites/default/files/omb/assets/omb/memoranda/fy2005/m05-24.pdf>)
  3. Information regarding background checks/badges ( <http://idbadge.nih.gov/background/index.asp>)

#### c. Position Sensitivity Levels:

This contract will entail the following position sensitivity levels:

**Level 6: Public Trust - High Risk.** Contractor/subcontractor employees assigned to Level 6 positions shall undergo a Suitability Determination and Background Investigation (MBI).

**Level 5: Public Trust - Moderate Risk.** Contractor/subcontractor employees assigned to Level 5 positions with no previous investigation and approval shall undergo a Suitability Determination and a Minimum Background Investigation (MBI), or a Limited Background Investigation (LBI).

**Level 1: Non-Sensitive.** Contractor/subcontractor employees assigned to Level 1 positions shall undergo a Suitability Determination and National Check and Inquiry Investigation (NACI).

- d. The personnel investigation procedures for Contractor personnel require that the Contractor prepare and submit background check/investigation forms based on the type of investigation required. The minimum Government investigation for a non-sensitive position is a National Agency Check and Inquiries (NACI) with fingerprinting. More restricted positions - i.e., those above non-sensitive, require more extensive documentation and investigation.

The Contractor shall submit a roster, by name, position, e-mail address, phone number and responsibility, of all staff (including subcontractor staff) working under the contract who will develop, have the ability to access and/or maintain a Federal Information System(s). The roster shall be submitted to the Contracting Officer's Representative (COR), with a copy to the Contracting Officer, within 14 calendar days after the effective date of the contract. The Contracting Officer shall notify the Contractor of the appropriate level of suitability investigations to be performed. An electronic template, "**Roster of Employees Requiring Suitability Investigations**," is available for contractor use at: [https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/SuitabilityRoster\\_10-15-12.xlsx](https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/SuitabilityRoster_10-15-12.xlsx).

Upon receipt of the Government's notification of applicable Suitability Investigations required, the Contractor shall complete and submit the required forms within 30 days of the notification.

The Contractor shall notify the Contracting Officer in advance when any new personnel, who are subject to a background check/investigation, will work under the contract and if they have previously been the subject of national agency checks or background investigations.

All contractor and subcontractor employees shall comply with the conditions established for their designated position sensitivity level prior to performing any work under this contract.

Contractors may begin work after the fingerprint check has been completed.

- e. Investigations are expensive and may delay performance, regardless of the outcome of the investigation. Delays associated with rejections and consequent re-investigations may not be excusable in accordance with the FAR clause, Excusable Delays - see FAR 52.249-14. Accordingly, the Contractor shall ensure that any additional employees whose names it submits for work under this contract have a reasonable chance for approval.
- f. Typically, the Government investigates personnel at no cost to the Contractor. However, multiple investigations for the same position may, at the Contracting Officer's discretion, justify reduction(s) in the contract price of no more than the cost of the additional investigation(s).
- g. The Contractor shall include language similar to this "HHS Controlled Facilities and Information Systems Security" language in all subcontracts that require subcontractor personnel to have the same frequency and duration of (1) physical access to an HHS-controlled facility; (2) logical access to an HHS-controlled information system; (3) access to sensitive HHS data/information, whether in an HHS-controlled information system or in hard copy; or (4) any combination of circumstances (1) through (3).
- h. The Contractor shall direct inquiries, including requests for forms and assistance, to the Contracting Officer or designee.
- i. Within 7 calendar days after the Government's final acceptance of the work under this contract, or upon termination of the contract, the Contractor shall return all identification badges to the Contracting Officer or designee.

**B. Standard for Encryption language, HHSAR 352.239-71, (January 2010)**

- a. The Contractor shall use Federal Information processing Standard (FIPS) 140-2-compliant encryption (Security) Requirements for Cryptographic Module, as amended) to protect all instances of HHS sensitive information during storage and transmission. (Note: The Government has determined that HHS information under this contract is considered "sensitive" in accordance with FIPS 199, Standards for Security Categorization of Federal Information and Information Systems, dated February 2004).
- b. The Contractor shall verify that the selected encryption product has been validated under the Cryptographic Module Validation Program (see <http://csrc.nist.gov/cryptval/>) to confirm compliance with FIPS 140-2 (as amended). The Contractor shall provide a written copy of the validation documentation to the Contracting Officer and the Contracting Officer's Technical Representative.
- c. The Contractor shall use the Key Management Key (see FIPS 201, Chapter 4, as amended) on the HHS personal identification verification (PIV) card; or alternatively, the Contractor shall establish and use a key recovery mechanism to ensure the ability for authorized personnel to decrypt and recover all encrypted information (see <http://csrc.nist.gov/drivers/documents/ombencryption-guidance.pdf>). The Contractor shall notify the Contracting Officer and the Contracting Officer's Technical Representative of personnel authorized to decrypt and recover all encrypted information.
- d. The Contractor shall securely generate and manage encryption keys to prevent unauthorized decryption of information in accordance with FIPS 140-2 (as amended).

- e. The Contractor shall ensure that this standard is incorporated into the Contractor's property management/ control system or establish a separate procedure to account for all laptop computers, desktop computers, and other mobile devices and portable media that store or process sensitive HHS information.
- f. The Contractor shall ensure that its subcontractors (all tiers) which perform work under this contract comply with the requirements contained in this clause.

**C. Security Requirements For Federal Information Technology Resources, HHSAR 352.239-72,**  
(January 2010)

- a. **Applicability.** This clause applies whether the entire contract or order (hereafter "contract"), or portion thereof, includes information technology resources or services in which the Contractor has physical or logical (electronic) access to, or operates a Department of Health and Human Services (HHS) system containing, information that directly supports HHS' mission. The term "information technology (IT)", as used in this clause, includes computers, ancillary equipment (including imaging peripherals, input, output, and storage devices necessary for security and surveillance), peripheral equipment designed to be controlled by the central processing unit of a computer, software, firmware and similar procedures, services (including support services) and related resources. This clause does not apply to national security systems as defined in FISMA.
- b. **Contractor responsibilities.** The Contractor is responsible for the following:
  - 1. Protecting Federal information and Federal information systems in order to ensure their -
    - a. Integrity, which means guarding against improper information modification or destruction, and includes ensuring information non-repudiation and authenticity;
    - b. Confidentiality, which means preserving authorized restrictions on access and disclosure, including means for protecting personal privacy and proprietary information; and
    - c. Availability, which means ensuring timely and reliable access to and use of information.
  - 2. Providing security of any Contractor systems, and information contained therein, connected to an HHS network or operated by the Contractor, regardless of location, on behalf of HHS.
  - 3. Adopting, and implementing, at a minimum, the policies, procedures, controls and standards of the HHS Information Security Program to ensure the integrity, confidentiality, and availability of Federal information and Federal information systems for which the Contractor is responsible under this contract or to which it may otherwise have access under this contract. The HHS Information Security Program is outlined in the HHS Information Security Program Policy, which is available on the HHS Office of the Chief Information Officer's (OCIO) Web site.
- c. **Personal identity verification.** The Contractor shall identify its employees with access to systems operated by the Contractor for HHS or connected to HHS systems and networks. The Contracting Officer's Representative (COR) shall identify, for those identified employees, position sensitivity levels that are commensurate with the responsibilities and risks associated with their assigned positions. The Contractor shall comply with the HSPD-12 requirements contained in "HHS-Controlled Facilities and Information Systems Security" requirements specified in the SOW/PWS of this contract.
- d. **Contractor and subcontractor employee training.** The Contractor shall ensure that its employees, and those of its subcontractors, performing under this contract complete HHS-furnished initial and refresher security and privacy education and awareness training before being granted access to systems operated by the Contractor on behalf of HHS or access to HHS systems and networks. The Contractor shall provide documentation to the COR evidencing that Contractor employees have completed the required training.
- e. **Government access for IT inspection.** The Contractor shall afford the Government access to the Contractor's and subcontractors' facilities, installations, operations, documentation, databases, and

personnel used in performance of this contract to the extent required to carry out a program of IT inspection (to include vulnerability testing), investigation, and audit to safeguard against threats and hazards to the integrity, confidentiality, and availability, of HHS data or to the protection of information systems operated on behalf of HHS.

- f. **Subcontracts.** The Contractor shall incorporate the substance of this clause in all subcontracts that require protection of Federal information and Federal information systems as described in paragraph (a) of this clause, including those subcontracts that -
  - a. Have physical or electronic access to HHS' computer systems, networks, or IT infrastructure; or
  - b. Use information systems to generate, store, process, or exchange data with HHS or on behalf of HHS, regardless of whether the data resides on a HHS or the Contractor's information system.
- g. **Contractor employment notice.** The Contractor shall immediately notify the Contracting Officer when an employee either begins or terminates employment (or is no longer assigned to the HHS project under this contract), if that employee has, or had, access to HHS information systems or data.
- h. **Document information.** The Contractor shall contact the Contracting Officer for any documents, information, or forms necessary to comply with the requirements of this clause.
- i. **Contractor responsibilities upon physical completion of the contract.** The Contractor shall return all HHS information and IT resources provided to the Contractor during contract performance and certify that all HHS information has been purged from Contractor-owned systems used in contract performance.
- j. **Failure to comply.** Failure on the part of the Contractor or its subcontractors to comply with the terms of this clause shall be grounds for the Contracting Officer to terminate this contract.

(End of Clause)

**Note:** The NIST Special Publication SP-800-26 cited in subparagraph c.1.a.(ii) of this clause has been superseded by NIST SP 800-53A, "Guide for Assessing the Security Controls in Federal Information Systems and Organizations" for use for the assessment of security control effectiveness. See <http://csrc.nist.gov/publications/PubsSPs.html> to access NIST Special Publications (800 Series).

#### D. Additional NIH Requirements

##### 1. INFORMATION SECURITY TRAINING

In addition to any training covered under paragraph (e) of HHSAR 352.239-72, the contractor shall comply with the below training:

###### a. Mandatory Training

- i. All Contractor employees having access to (1) Federal information or a Federal information system or (2) sensitive data/information as defined at HHSAR 304.1300(a) (4), shall complete the NIH Computer Security Awareness Training course at <http://irtsectraining.nih.gov/> before performing any work under this contract. Thereafter, Contractor employees having access to the information identified above shall complete an annual NIH-specified refresher course during the life of this contract. The Contractor shall also ensure subcontractor compliance with this training requirement.
- ii. The Contractor shall maintain a listing by name and title of each Contractor/Subcontractor employee working on this contract and having access of the kind in paragraph 1.a(1) above, who has completed the NIH required training. Any additional security training completed by the Contractor/Subcontractor staff shall be included on this listing. The list shall be provided to the COR and/or Contracting Officer upon request.

b. Role-based Training

HHS requires role-based training when responsibilities associated with a given role or position, could, upon execution, have the potential to adversely impact the security posture of one or more HHS systems. Read further guidance about "NIH Information Security Awareness and Training Policy," at: <https://ocio.nih.gov/InfoSecurity/Policy/Documents/Final-InfoSecAwarenessTrainPol.doc>.

The Contractor shall maintain a list of all information security training completed by each contractor/subcontractor employee working under this contract. The list shall be provided to the COR and/or Contracting Officer upon request.

c. Rules of Behavior

The Contractor shall ensure that all employees, including subcontractor employees, comply with the NIH Information Technology General Rules of Behavior ( <https://ocio.nih.gov/InfoSecurity/training/Pages/nihitrob.aspx>), which are contained in the NIH Information Security Awareness Training Course <http://irtsectraining.nih.gov>.

## 2. PERSONNEL SECURITY RESPONSIBILITIES

In addition to any personnel security responsibilities covered under HHSAR 352.239-72, the contractor shall comply with the below personnel security responsibilities:

- a. In accordance with Paragraph (h) of HHSAR 352.239-72, the Contractor shall notify the Contracting officer and the COR **within five working days** before a new employee assumes a position that requires access to HHS information systems or data, or when an employee with such access stops working on this contract. The Government will initiate a background investigation on new employees assuming a position that requires access to HHS information systems or data, and will stop pending background investigations for employees that no longer work under the contract or no longer have such access.
- b. **New contractor employees who have or will have access to HHS information systems or data:** The Contractor shall provide the COR with the name, position title, e-mail address, and phone number of all new contract employees working under the contract and provide the name, position title and position sensitivity level held by the former incumbent. If an employee is filling a new position, the Contractor shall provide a position description and the Government will determine the appropriate position sensitivity level.
- c. **Departing contractor employees:** The Contractor shall provide the COR with the name, position title, and position sensitivity level held by or pending for departing employees. The Contractor shall perform and document the actions identified in the Contractor Employee Separation Checklist (<https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/Emp-sep-checklist.pdf>) when a Contractor/subcontractor employee terminates work under this contract. All documentation shall be made available to the COR upon request.
- d. **Commitment to Protect Non-Public Departmental Information and Data.**  

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

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

Each employee, including subcontractors, having access to non-public Department

information under this acquisition shall complete the "Commitment to Protect Non-Public Information - Contractor Employee Agreement" located at:

<https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/Nondisclosure.pdf>.

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

### 3. LOSS AND/OR DISCLOSURE OF PERSONALLY IDENTIFIABLE INFORMATION (PII) - NOTIFICATION OF DATA BREACH

The Contractor shall report all suspected or confirmed incidents involving the loss and/or disclosure of PII in electronic or physical form. Notification shall be made to the NIH Incident Response Team (IRT) via email ([IRT@mail.nih.gov](mailto:IRT@mail.nih.gov)) within one hour of discovering the incident. The Contractor shall follow up with IRT by completing and submitting one of the applicable two forms below within three (3) work days of incident discovery:

NIH PII Spillage Report at: [https://ocio.nih.gov/InfoSecurity/Policy/Documents/NIH\\_PII\\_Spillage\\_Proced.doc](https://ocio.nih.gov/InfoSecurity/Policy/Documents/NIH_PII_Spillage_Proced.doc)

NIH Lost or Stolen Assets Report at: [https://ocio.nih.gov/InfoSecurity/Policy/Documents/ISSO\\_Stolen\\_Device-Media\\_Handling\\_Procedures.doc](https://ocio.nih.gov/InfoSecurity/Policy/Documents/ISSO_Stolen_Device-Media_Handling_Procedures.doc)

### ARTICLE H.9. 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 Clause 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 by the last day of the base contract and each option period.

[End of HHSAR 352.239-73(c)]

**ARTICLE H.10. ACCESS TO NATIONAL INSTITUTES OF HEALTH (NIH) ELECTRONIC MAIL**

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

**ARTICLE H.11. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE**

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

**ARTICLE H.12. YEAR 2000 COMPLIANCE**

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

**1. Service Involving the Use of Information Technology**

**YEAR 2000 COMPLIANCE--SERVICE INVOLVING THE USE OF INFORMATION TECHNOLOGY**

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

(End of Clause)

**PART II - CONTRACT CLAUSES SECTION I - CONTRACT CLAUSES**

THE FOLLOWING ARTICLE I.1. GENERAL CLAUSE LISTING MAY 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.

**ARTICLE I.1. GENERAL CLAUSES FOR A COST-REIMBURSEMENT CONTRACT WITH NON- PROFIT ORGANIZATIONS OTHER THAN EDUCATIONAL INSTITUTIONS****a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES**

<u>CLAUSE NO.</u>	<u>DATE</u>	<u>TITLE</u>
FAR 52.202-1	Nov 2013	Definitions (Over the Simplified Acquisition Threshold)
FAR 52.203-3	Apr 1984	Gratuities (Over the Simplified Acquisition Threshold)
FAR 52.203-5	Apr 1984	Covenant Against Contingent Fees (Over the Simplified Acquisition Threshold)
FAR 52.203-6	Sep 2006	Restrictions on Subcontractor Sales to the Government (Over the Simplified Acquisition Threshold)
FAR 52.203-7	Oct 2010	Anti-Kickback Procedures (Over the Simplified Acquisition Threshold)
FAR 52.203-8	Jan 1997	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Over the Simplified Acquisition Threshold)
FAR 52.203-10	Jan 1997	Price or Fee Adjustment for Illegal or Improper Activity (Over the Simplified Acquisition Threshold)
FAR 52.203-12	Oct 2010	Limitation on Payments to Influence Certain Federal Transactions (Over \$150,000)
FAR 52.203-17	Sep 2013	Contractor Employee Whistleblower Rights and Requirements to Inform Employees of Whistleblower Rights (Over the Simplified Acquisition Threshold)
FAR 52.204-4	May 2011	Printed or Copied Double-Sided on Postconsumer Fiber Content Paper(Over the Simplified Acquisition Threshold)
FAR 52.204-10	Jul 2013	Reporting Executive Compensation and First-Tier Subcontract Awards (\$25,000 or more)
FAR 52.204-13	Jul 2013	System for Award Management Maintenance
FAR 52.209-6	Aug 2013	Protecting the Government's Interest When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (Over \$30,000)
FAR 52.215-2	Oct 2010	Audit and Records - Negotiation [Note: Applies to ALL contracts funded in whole or in part with Recovery Act funds, regardless of dollar value, AND contracts over the Simplified Acquisition Threshold funded exclusively with non-Recovery Act funds.], Alternate II (Apr 1998)
FAR 52.215-8	Oct 1997	Order of Precedence - Uniform Contract Format
FAR 52.215-10	Aug 2011	Price Reduction for Defective Certified Cost or Pricing Data (Over \$700,000)
FAR 52.215-12	Oct 2010	Subcontractor Cost or Pricing Data (Over \$700,000)
FAR 52.215-14	Oct 2010	Integrity of Unit Prices (Over the Simplified Acquisition Threshold)
FAR 52.215-15	Oct 2010	Pension Adjustments and Asset Reversions (Over \$700,000)
FAR 52.215-18	Jul 2005	Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) other than Pensions
FAR 52.215-19	Oct 1997	Notification of Ownership Changes
FAR 52.215-21	Oct 2010	Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data - Modifications
FAR 52.215-23	Oct 2009	Limitations on Pass-Through Charges (Over the Simplified Acquisition Threshold)
FAR 52.216-7	Jun 2013	Allowable Cost and Payment, Alternate IV (Aug 2012)
FAR 52.216-11	Apr 1984	Cost Contract - No Fee
FAR 52.219-8	Jul 2013	Utilization of Small Business Concerns (Over the Simplified Acquisition Threshold)
FAR 52.219-9	Jul 2013	Small Business Subcontracting Plan (Over \$650,000, \$1.5 million for Construction)

FAR 52.219-16	Jan 1999	Liquidated Damages - Subcontracting Plan (Over \$650,000, \$1.5 million for Construction)
FAR 52.222-2	Jul 1990	Payment for Overtime Premium (Over the Simplified Acquisition Threshold) (Note: The dollar amount in paragraph (a) of this clause is \$0 unless otherwise specified in the contract.)
FAR 52.222-3	Jun 2003	Convict Labor
FAR 52.222-21	Feb 1999	Prohibition of Segregated Facilities
FAR 52.222-26	Mar 2007	Equal Opportunity
FAR 52.222-35	Sep 2010	Equal Opportunity for Veterans (\$100,000 or more)
FAR 52.222-36	Oct 2010	Affirmative Action for Workers with Disabilities
FAR 52.222-37	Sep 2010	Employment Reports on Veterans (\$100,000 or more)
FAR 52.222-40	Dec 2010	Notification of Employee Rights Under the National Labor Relations Act (Over the Simplified Acquisition Threshold)
FAR 52.222-50	Feb 2009	Combating Trafficking in Persons
FAR 52.222-54	Aug 2013	Employment Eligibility Verification (Over the Simplified Acquisition Threshold)
FAR 52.223-6	May 2001	Drug-Free Workplace
FAR 52.223-18	Aug 2011	Encouraging Contractor Policies to Ban Text Messaging While Driving
FAR 52.225-1	Feb 2009	Buy American Act - Supplies
FAR 52.225-13	Jun 2008	Restrictions on Certain Foreign Purchases
FAR 52.227-1	Dec 2007	Authorization and Consent, Alternate I (Apr 1984)
FAR 52.227-2	Dec 2007	Notice and Assistance Regarding Patent and Copyright Infringement
FAR 52.227-11	Dec 2007	Patent Rights - Ownership by the Contractor (Note: In accordance with FAR 27.303(b)(2), paragraph (e) is modified to include the requirements in FAR 27.303(b)(2)(i) through (iv). The frequency of reporting in (i) is annual.
FAR 52.227-14	Dec 2007	Rights in Data - General, Alternate IV (Dec 2007)
FAR 52.232-9	Apr 1984	Limitation on Withholding of Payments
FAR 52.232-20	Apr 1984	Limitation of Cost
FAR 52.232-23	Jan 1986	Assignment of Claims
FAR 52.232-25	Jul 2013	Prompt Payment, Alternate I (Feb 2002)
FAR 52.232-33	Jul 2013	Payment by Electronic Funds Transfer--System for Award Management
FAR 52.232-39	Jun 2013	Unenforceability of Unauthorized Obligations
FAR 52.233-1	Jul 2002	Disputes
FAR 52.233-3	Aug 1996	Protest After Award, Alternate I (Jun 1985)
FAR 52.233-4	Oct 2004	Applicable Law for Breach of Contract Claim
FAR 52.242-1	Apr 1984	Notice of Intent to Disallow Costs
FAR 52.242-3	May 2001	Penalties for Unallowable Costs (Over \$700,000)
FAR 52.242-4	Jan 1997	Certification of Final Indirect Costs
FAR 52.242-13	Jul 1995	Bankruptcy (Over the Simplified Acquisition Threshold)
FAR 52.243-2	Aug 1987	Changes - Cost Reimbursement, Alternate V (Apr 1984)
FAR 52.244-2	Oct 2010	Subcontracts (Over the Simplified Acquisition Threshold), Alternate I (June 2007)
FAR 52.244-5	Dec 1996	Competition in Subcontracting (Over the Simplified Acquisition Threshold)
FAR 52.244-6	Dec 2013	Subcontracts for Commercial Items
FAR 52.245-1	Apr 2012	Government Property, Alternate II (April 2012)
FAR 52.245-9	Apr 2012	Use and Charges
FAR 52.246-23	Feb 1997	Limitation of Liability (Over the Simplified Acquisition Threshold)
FAR 52.249-6	May 2004	Termination (Cost-Reimbursement)
FAR 52.249-14	Apr 1984	Excusable Delays
FAR 52.253-1	Jan 1991	Computer Generated Forms

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

<u>CLAUSE NO.</u>	<u>DATE</u>	<u>TITLE</u>
HHSAR 352.202-1	Jan 2006	Definitions - with Alternate paragraph (h) (Jan 2006)
HHSAR 352.203-70	Mar 2012	Anti-Lobbying
HHSAR 352.216-70	Jan 2006	Additional Cost Principles
HHSAR 352.222-70	Jan 2010	Contractor Cooperation in Equal Employment Opportunity Investigations

HHSAR 352.227-70	Jan 2006	Publications and Publicity
HHSAR 352.228-7	Dec 1991	Insurance - Liability to Third Persons
HHSAR 352.233-71	Jan 2006	Litigation and Claims
HHSAR 352.242-70	Jan 2006	Key Personnel
HHSAR 352.242-73	Jan 2006	Withholding of Contract Payments
HHSAR 352.242-74	Apr 1984	Final Decisions on Audit Findings

## 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 I** (April 1984), of FAR Clause **52.227-1, Authorization and Consent** (December 2007) is deleted in its entirety.
- b. FAR Clause **52.227-11, Patent Rights--Ownership by the Contractor** (December 2007) is deleted in its entirety.
- c. **Alternate IV** (December 2007), of FAR Clause **52.227-14, Rights In Data--General** (December 2007) is deleted in its entirety.
- d. **Alternate II** (April 2012), of FAR Clause **52.245-1, Government Property** (April 2012) is deleted in its entirety.

## 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** (April 2010).
2. FAR Clause **52.217-9, Option to Extend the Term of the Contract** (March 2000).

a) The Government may unilaterally exercise any of the Term Options contained in Article B.2(b) provided that the Government gives the Contractor a preliminary written notice of its intent to exercise said option at least 30 days prior to contract expiration. (Should it be the Government's intent to NOT exercise the next subsequent Term Option contained in Article B.2(b), the Government will notify the contractor at least 45 days prior to contract expiration in order to allow for the preparation of any final contract deliverables). The preliminary notice does not commit the Government to exercise the referenced Option.

(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 five (5) years.

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

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

[ ] Offeror elects to waive the evaluation preference."

4. FAR Clause **52.219-28, Post-Award Small Business Program Rerepresentation** (July 2013).

5. FAR Clause **52.227-17, Rights in Data--Special Works** (December 2007).
  6. FAR Clause **52.242-3, Penalties for Unallowable Costs** (May 2001).
- b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CHAPTER 3) CLAUSES:
1. HHSAR Clause **352.219-71, Mentor-Protégé Program Reporting Requirements** (January 2010).
  2. HHSAR Clause **352.231-70, Salary Rate Limitation** (August 2012).

**Note:** P.L. 112-74 sets forth the Salary Rate Limitation at the Executive Level II Rate, effective December 23, 2011.

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

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

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

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

1. **NIH(RC)-11, Research Patient Care Costs** (4/1/84).

#### **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.

- 1) FAR Clause **52.209-9, Updates of Publicly Available Information Regarding Responsibility Matters** (July 2013)
  - a. The Contractor shall update the information in the Federal Awardee Performance and Integrity Information System (FAPIIS) 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 FAPIIS on or after April 15, 2011, except past performance reviews, will be publicly available. FAPIIS 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 FAPIIS is automatically transferred after a waiting period of 14 calendar days, except for--



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

**SECTION J - LIST OF ATTACHMENTS**

The following documents are incorporated into this RFP:

**SOLICITATION ATTACHMENTS**

<b>Attachment No.</b>	<b>Title</b>	<b>Location</b>
Attachment 1:	Packaging and Delivery of Proposal (Non R& D)	Attached (1 page)
Attachment 2:	Section K – Addendum Representations, Certifications, and Other Statements of Offerors	Attached (11 pages)
Attachment 3:	Proposal Summary and Data Record NIH-2043	<a href="http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/NIH2043.pdf">http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/NIH2043.pdf</a>

**TECHNICAL PROPOSAL ATTACHMENTS**

<b>Attachment No.</b>	<b>Title</b>	<b>Location</b>
Attachment 4:	Summary of Related Activities	<a href="http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/summary-related-activities.pdf">http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/summary-related-activities.pdf</a>
Attachment 5:	Protection of Human Subject Assurance Identification/IRB Certification/Declaration of Exemption, OMB Form No. 0990-0263 (Formerly Optional Form 310)	<a href="http://www.hhs.gov/ohrp/assurances/forms/of310.pdf">http://www.hhs.gov/ohrp/assurances/forms/of310.pdf</a>
Attachment 6:	HHS Section 508 Product Assessment Template	<a href="http://www.hhs.gov/web/508/contracting/technology/vendors.html">http://www.hhs.gov/web/508/contracting/technology/vendors.html</a>

**BUSINESS PROPOSAL ATTACHMENTS**

<b>Attachment No.</b>	<b>Title</b>	<b>Location</b>
Attachment 7:	Total Cost Summary Business Proposal Budget Template	Attached (2 pages)
Attachment 8:	Small Business Subcontracting Plan	<a href="http://www.hhs.gov/about/smallbusiness/subcontractplan.html">http://www.hhs.gov/about/smallbusiness/subcontractplan.html</a>
Attachment 9:	Disclosure of Lobbying Activities, OMB Form SF-LLL	<a href="http://www.gsa.gov/portal/forms/download/116430">http://www.gsa.gov/portal/forms/download/116430</a>
Attachment 10:	Small Disadvantaged Business Participation Factor	Attached (1 page)

**INFORMATIONAL ATTACHMENTS**

<b>Attachment No.</b>	<b>Title</b>	<b>Location</b>
Attachment 11:	Invoice/Financing Request and Contract Financial Reporting Instructions--Cost Reimbursement, NIH(RC)-4	<a href="http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/rc4_508.pdf">http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/rc4_508.pdf</a>
Attachment 12:	Research Patient Care Costs, NIH(RC)-11	<a href="http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/rc11.pdf">http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/rc11.pdf</a>
Attachment 13:	Commitment to Protect Non-Public Information Contractor Agreement	Attached (2 pages)
Attachment 14:	Roster of Employees Requiring Suitability Investigations	<a href="https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/SuitabilityRoster_10-15-12.xlsx">https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/SuitabilityRoster_10-15-12.xlsx</a>
Attachment 15:	Employee Separation Checklist	Attached (1 page)

**PACKAGING AND DELIVERY OF PROPOSALS**

Your proposal shall be prepared and organized in accordance with SECTION L.- Instructions, Conditions, and Notices to Offerors,” of the RFP. Marking, copies, shipment and delivery of proposals shall be as indicated below.

Proposals for furnishing the supplies and/or services in the SCHEDULE will be accepted at the location specified below, and in the number of copies specified until 5:00 pm (EST), June 9, 2014.

**EXTERNAL PACKAGE MARKING**

In addition to the address cited below, the outside of each package should be marked with the following information:

**“RFP NO. NIH-NINDS-14-01”**

**“TO BE OPENED BY AUTHORIZED GOVERNMENT PERSONNEL ONLY”**

**NUMBER OF COPIES**

**TECHNICAL PROPOSAL: ORIGINAL AND SIX (6) COPIES**

**BUSINESS PROPOSAL: ORIGINAL AND SIX (6) COPIES**

**DELIVERY ADDRESS****If hand-delivered or delivery service**

Contracting Officer  
Office of Acquisitions, Neurosciences  
NINDS R&D CMB, NIDA, NIH  
6001 Executive Blvd., Suite 3287  
Rockville, MD 20852

**If using U.S. Postal Service**

Contracting Officer  
Office of Acquisitions, Neurosciences  
NINDS R&D CMB, NIDA, NIH  
6001 Executive Blvd., Suite 3287, MSC 9531  
Bethesda, MD 20892-9531

**NOTE:** Please be aware that the U.S. Postal Service’s “Express Mail” **DOES NOT** deliver to the Rockville, Maryland address **AND** delivery to the Bethesda, Maryland address will result in a delayed delivery to our office in Rockville, MD (up to 3 – 5 days). If a proposal is not received by the RFP receipt date and time, it will be considered a “late proposal.”

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

Updated through FAC 2005-72

Last updated: 02/2014

This SECTION is made up of six parts as follows:

1. Annual Representations and Certifications, FAR 52.204-8
2. Information Regarding Responsibility Matters, FAR 52.209-7
3. Cost Accounting Standards
4. Certification Regarding Environmental Tobacco Smoke
5. Certification of Institutional on Financial Conflicts of Interest
6. Disaster or Emergency Area Representation
7. Alternate – Representation by Corporations Regarding an Unpaid Delinquent Tax Liability or a Felony Conviction Under Any Federal Law
8. Representation of Limited Rights Data and Restricted Computer Software, FAR 52.227-15

**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 (DEC 2013), 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. This provision applies to solicitations using funds appropriated in fiscal years 2008, 2009, 2010 or 2012.
- (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 Act Certificate. This provision applies to solicitations containing the clause at 52.225-1.
  - (xvii) 52.225-4, Buy American Act--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 \$79,507, the provision with its Alternate II applies.
    - (D) If the acquisition value is \$79,507 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—
    - (A) Solicitations for research, studies, supplies, or services of the type normally acquired from higher educational institutions; and
    - (B) For DoD, NASA, and Coast Guard acquisitions, solicitations that contain the clause at 52.219-23, Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns.
- (2) The following certifications are applicable as indicated by the Contracting Officer: *[Contracting Officer check as appropriate.]*

- \_\_\_(i) 52.219-22, Small Disadvantaged Business Status.
  - \_\_\_(A) Basic.
  - \_\_\_(B) Alternate I.
- \_\_\_(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 Act to Contracts for Maintenance, Calibration, or Repair of Certain Equipment Certification.
- \_\_\_(iv) 52.222-52 Exemption from Application of the Service Contract Act 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. 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](http://www.acquisition.gov) (see 52.204-7).

### 3. COST ACCOUNTING STANDARDS

- (1) **Cost Accounting Standards Notices and Certification** (May 2012), 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 \$700,000 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.**

(5) **Certificate of Disclosure Statement Due Date by Educational Institution.**  
**(ALTERNATE I - April 1996)**

If the offeror is an educational institution that, under the transition provisions of 48 CFR 9903- 202-1(f), is or will be required to submit a Disclosure Statement after receipt of this award, the offeror hereby certifies that (**check one and complete**):

- (i) A Disclosure Statement filing Due Date of \_\_\_\_\_ has been established with the cognizant Federal agency.
- (ii) The Disclosure Statement will be submitted within the 6-month period ending \_\_\_\_\_ months after receipt of this award.

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

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

## 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.

## 4. **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.

## 5. 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.

## 6. 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)

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

The Consolidated Appropriations Act, 2012 Pub. L 112-74 and the Consolidated and Further Continuing Appropriations Act, Pub. L 112-55 prohibit covered agencies from using funds to enter into contracts with corporations with have 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)

**8. REPRESENTATION OF LIMITED RIGHTS DATA AND RESTRICTED COMPUTER SOFTWARE (DEC 2007), FAR provision 52.227-15**

(a) This solicitation sets forth the Government’s known delivery requirements for data (as defined in the Deviated FAR clause at [52.227-14](#), Rights in Data—General). Any resulting contract may also provide the Government the option to order additional data under the Additional Data Requirements clause at [52.227-16](#), if included in the contract. Any data delivered under the resulting contract will be subject to

the Deviated FAR clause at [52.227-14](#) Rights in Data—General included in this contract. Under the latter clause, a Contractor may withhold from delivery data that qualify as limited rights data or restricted computer software, and deliver form, fit, and function data instead. The latter clause also may be used with its Alternates II and/or III to obtain delivery of limited rights data or restricted computer software, marked with limited rights or restricted rights notices, as appropriate. In addition, use of Alternate V with this latter clause provides the Government the right to inspect such data at the Contractor's facility.

(b) By completing the remainder of this paragraph, the Offeror represents that it has reviewed the requirements for the delivery of technical data or computer software and states [*Offeror check appropriate block*]—

(1) None of the data proposed for fulfilling the data delivery requirements qualifies as limited rights data or restricted computer software; or

(2) Data proposed for fulfilling the data delivery requirements qualify as limited rights data or restricted computer software and are identified as follows:

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(c) Any identification of limited rights data or restricted computer software in the Offeror's response is not determinative of the status of the data should a contract be awarded to the Offeror.

(End of provision)

**ATTACHMENT NO. 7****TOTAL COST SUMMARY– BUSINESS PROPOSAL BUDGET TEMPLATE**

COST ELEMENTS	BASE	OPTION 1 YEAR 02	OPTION 2 YEAR 03	OPTION 3 YEAR 04	OPTION 4 YEAR 05	TOTAL
	CONTRACT YEAR 01					
<b>DIRECT LABOR</b> (List all individuals by name/labor category. Indicate hours, % effort, and rates for each.)						
_____	\$	\$	\$	\$	\$	\$
_____	\$	\$	\$	\$	\$	\$
_____	\$	\$	\$	\$	\$	\$
_____	\$	\$	\$	\$	\$	\$
_____	\$	\$	\$	\$	\$	\$
_____	\$	\$	\$	\$	\$	\$
_____	\$	\$	\$	\$	\$	\$
<b>DIRECT LABOR COSTS</b>	\$	\$	\$	\$	\$	\$
<b>FRINGE BENEFITS**</b>	\$	\$	\$	\$	\$	\$
<b>MATERIALS/SUPPLIES</b> (Specify items and cost for each.)						
<b>TRAVEL COSTS</b> (Specify trips and costs.)	\$	\$	\$	\$	\$	\$
<b>EQUIPMENT</b> (List separately)	\$	\$	\$	\$	\$	\$
<b>CONSULTANTS</b> (Identify name & amount)	\$	\$	\$	\$	\$	\$
<b>SUBCONTRACTS</b> (Identify name & amount)	\$	\$	\$	\$	\$	\$
<b>OTHER DIRECT COST</b> (Specify items & costs for all elements)	\$	\$	\$	\$	\$	\$
<b>TOTAL DIRECT COST</b>	\$	\$	\$	\$	\$	\$
<b>OVERHEAD ( %)**</b>	\$	\$	\$	\$	\$	\$
<b>TOTAL EST. COST</b>	\$	\$	\$	\$	\$	\$

**Specific Instructions:**

1. Enter dollar estimates for each person/labor category under Direct Labor. Hours or percent of effort estimates must be indicated for all employees. Offeror's proposal should be stated in the same terms as will be used to account for and record direct labor under the proposed contract and consistent with the time and effort accounting practices. If percentages of effort are used, the basis to which such percentages are applied must also be submitted by the offeror. If a pool of personnel is proposed, list the composition of the pool and how the cost proposed was calculated. List any factor used for prorating escalation rates for future years. Source documentation, e.g., payroll stubs, employee contracts, payroll verification forms, etc. shall be provided with the business proposal to substantiate the salary/hourly rates proposed for all employees.
2. **\*\*Fringe Benefits and Overhead** – list the rates applied and the base the rate is applied to. Provide copy of most recent negotiated overhead rate agreement with your cognizant federal agency.
3. This form must be included with the BUSINESS PROPOSAL.



**ATTACHMENT No. 13****CONTRACTOR NON-DISCLOSURE AGREEMENT (NDA)**

Each contractor/subcontractor who may have access to non-public information under their contract must sign the form: *Commitment to Protect Non-Public Information – Contractor Agreement*<sup>1</sup>. *The Agreement is on the next page.*

Please be aware that separate *Agreements* are required for each contract. *For NIH contractors registered in the NIH Enterprise Directory (NED) system:*

- The NDA is now included in the full and refresher version of the NIH Security Awareness courses.
- The NDA is also available for direct electronic acceptance from the menu within the Security and Privacy Awareness Training system.
- **Note:** NIH contractors who will not be receiving an Active Directory (network) account can also use the NDA form on the next page.

*For NIH contractors who are NOT registered in the NED system:*

- The NDA form on the following page shall be used.
- The printed copy of the form must be signed and submitted to your Project Officer prior to performing any work on the contract. Other copies are retained and/or submitted as stated in the *Agreement*.

Note: Contractors are no longer required to upload a copy of their *Agreement* into the Security Awareness Tracking System.

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<sup>1</sup> [HHS Rules of Behavior: HHS-OCIO-2010-0002.001S](#) and [HHS Contractor Oversight Guide, Appendix K](#)



## EMPLOYEE SEPARATION CHECKLIST

Contractor: \_\_\_\_\_ Contract No: \_\_\_\_\_

Departing Staff Member's Name: \_\_\_\_\_ Separation Date: \_\_\_\_\_

Check and complete one of the columns below as appropriate:

I. FRIENDLY SEPARATION		II. UNFRIENDLY SEPARATION	
Date (Mandatory)	Action	Date (Mandatory)	Action
	Remove all network and system access privileges.		Disable system access as quickly as possible—preferably just before the individual is notified of his or her dismissal.
	Collect any authentication tokens.		Terminate access to systems immediately when an employee notifies the Department of a resignation that is on unfriendly terms.
	Retrieve any access cards or Departmental identification badges.		Notify support functions (e.g., help desk) that an employee is no longer authorized access.
	Recover all keys.		Restrict the area and function of employees during the period between termination and leaving.
	Brief employee on continuing confidentiality and privacy responsibilities.		Immediately notify the Project Officer, appropriate NIH security officials, and the assigned IT Systems Manager of the time of removal.
	Review any employee contracts that remain valid after separation.		Request the Project Officer to have the combinations changed on all locks to which the contractor employee has access.
	Return property belonging to the United States Government.		Collect any authentication tokens.
	Identify any unique problems, filing schemes, or data backups created by the employee.		Retrieve any access cards or Departmental identification badges.
	Instruct employees on proper “clean up” procedures for their personal computers (PC) before leaving.		Recover all keys.
	Determine the employee's access termination date, and notify the Project Officer, appropriate NIH security officials, and the assigned IT Systems Manager within 24 hours of the time of termination.		Review the employee's duties and responsibilities under this contract with the Project Officer and assess the level of risk to the Government.
	Notify the Project Officer in writing upon completion of these actions.		Escort individual off premises in cases where the potential for retaliation is high.
			Notify the Project Officer in writing upon completion of these actions.

**CERTIFICATION:** By signing below, I certify that the above actions were taken on the dates indicated.\_\_\_\_\_  
Signature and Date\_\_\_\_\_  
Typed Name of Individual Authorized to Certify for Contractor\_\_\_\_\_  
Title of Individual Authorized to Certify for Contractor

**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 on-line Representations and Certifications. The SAM website may be accessed at: <http://www.sam.gov>; and
2. **INCLUDE as part of your BUSINESS PROPOSAL, a completed and signed copy of SECTION K – ADDENDUM REPRESENTATIONS, CERTIFICATIONS, AND OTHER STATEMENTS OF OFFERORS** provided as Attachment No. 2 under this solicitation.

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

**End of the Uniform Contract Schedule**

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

**1. GENERAL INFORMATION**

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

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

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

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

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

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

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

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

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

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

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

(i) The solicitation number;

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

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

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

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

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

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

(ii) (A) Any proposal, modification, or revision received at the Government office

designated in the solicitation after the exact time specified for receipt of offers is "late" and will not be considered unless it is received before award is made, the Contracting Officer determines that accepting the late offer would not unduly delay the acquisition; and—

- (1) If it was transmitted through an electronic commerce method authorized by the solicitation, it was received at the initial point of entry to the Government infrastructure not later than 5:00 p.m. one working day prior to the date specified for receipt of proposals; or
- (2) There is acceptable evidence to establish that it was received at the Government installation designated for receipt of offers and was under the Government's control prior to the time set for receipt of offers; or
- (3) It is the only proposal received.

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

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

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

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

- (4) Unless otherwise specified in the solicitation, the offeror may propose to provide any item or combination of items.
- (5) Offerors shall submit proposals in response to this solicitation in English, unless otherwise permitted by the solicitation, and in U.S. dollars, unless the provision at FAR 52.225-17, Evaluation of Foreign Currency Offers, is included in the solicitation.
- (6) Offerors may submit modifications to their proposals at any time before the solicitation closing date and time, and may submit modifications in response to an amendment, or to correct a mistake at any time before award.
- (7) Offerors may submit revised proposals only if requested or allowed by the Contracting Officer.
- (8) Proposals may be withdrawn at any time before award. Withdrawals are effective upon receipt of notice by the Contracting Officer.

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

e. Restriction on disclosure and use of data.

- (1) The proposal submitted in response to this request may contain data (trade secrets; business data (e.g., commercial information, financial information, cost and pricing data); and technical data)

which the offeror, including its prospective subcontractor(s), does not want used or disclosed for any purpose other than for evaluation of the proposal. The use and disclosure of any data may be so restricted; provided, that the Government determines that the data is not required to be disclosed under the Freedom of Information Act, 5 U.S.C. 552, as amended, and the offeror marks the cover sheet of the proposal with the following statements, specifying the particular portions of the proposal which are to be restricted:

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

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

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

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

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

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

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

f. Contract award.

(1) The Government intends to award a contract or contracts resulting from this solicitation to the responsible offeror(s) whose proposal(s) represents the best value after evaluation in accordance with the factors and sub-factors 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 622110.
2. The small business size standard is \$35.5 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 or about 9/1/2014.
2. It is anticipated that the awards from this solicitation will be multiple-year cost-reimbursement type, level of effort type contracts, with a base period of 12 months plus four one-year term options.
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. LEVEL OF EFFORT**

Prospective offerors are advised that the Government has outlined what we believe are the requisite labor types and mix of personnel that are needed for the clinical support services to be provided under the contract. This information is provided in Section "D" of the Statement of Work, entitled: "Clinical Support Roles and Responsibilities."

Offerors are requested to furnish their estimates of personnel and effort based upon the requirements of the Statement of Work and the proposed approach offered for achieving the stated objectives. The Government realizes that labor mix and respective levels of effort may vary between offerors depending on their organizational structure and approach to provide the requisite services. Offerors are required to provide written justification for the types and mix of personnel and their respective levels of effort in both their technical and business proposals.

**e. COMMITMENT OF PUBLIC FUNDS**

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

**f. COMMUNICATIONS PRIOR TO CONTRACT AWARD**

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

**g. RELEASE OF INFORMATION**

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

**h. PREPARATION COSTS**

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

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

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

Contracting Officer  
Office of Acquisitions,  
Neurosciences  
NINDS R&D CMB, NIDA, NIH  
6001 Executive Blvd. Room 3287  
Bethesda, MD 20892 MSC 9315

(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**

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

**1. Contract Type and General Clauses**

It is contemplated that a multiple-year cost-reimbursement type, level of effort type contracts, with a base period of 12 months plus four one-year term options will be awarded. 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

those relevant attachments 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 those relevant attachments 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 Attachment #3 in Section J).

#### 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. 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](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:

- I. to the cognizant audit agency and the Government Accountability Office for auditing.
- II. to the Department of Justice as required for litigation.
- III. to respond to congressional inquiries.
- IV. 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 proposal will be evaluated by a technical evaluation panel. The panel will evaluate each technical proposal in strict conformity with the technical evaluation criteria of the RFP, utilizing point scores and written critiques. The strengths and weaknesses of each proposal will be addressed by the reviewers and written recommendations provided to the Contracting Officer. Each proposal will be rated as either technically acceptable or unacceptable. Proposals rated technically unacceptable will not be considered further. The panel may suggest that the Contracting Officer request clarifying information from an offeror. Considering the nature and complexity of this requirement and the need to insure the complete understanding and agreement as to the technical performance objectives, the Government reserves the right to conduct pre-award site visits to any offeror(s) included in the competitive range.
- b. A separate and independent review of the business proposal will be made and will be subjected to a cost realism analysis, and if applicable, a cost analysis.
- 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 discussions are conducted 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 NINDS's policy to conduct discussions with all offerors in the competitive range, NINDS 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 Government reserving the right to finalize details with a selected offeror, if necessary, 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 NINDS 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 NINDS requirements. Synopses of awards exceeding \$25,000 will be published in FedBizOpps.

## 12. Past Performance Information

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

A list of contracts completed during the past three years and ALL contracts currently being performed that are identical or similar in nature to the Statement of Work (SOW) requirements of this solicitation. Contracts listed may include those entered into by the Federal Government, agencies of state and local governments, non-profit entities, 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 subcontractor who performs the identical or similar work as outlined in the SOW regardless of dollar value.

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.

13. **Information and Physical Access Security** is applicable to this solicitation and the following information is provided to assist in proposal preparation.

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

The Homeland Security Presidential Directive (HSPD)-12 and the Federal Information Security Management Act of 2002 (P.L. 107-347) (FISMA) requires each agency to develop, document, and implement an agency-wide information security program to safeguard information and information systems that support the operations and assets of the agency, including those provided or managed by another agency, contractor (including subcontractor), or other source.

### A. HHS-Controlled Facilities and Information Systems Security

- a. To perform the work specified herein, Contractor personnel are expected to have routine (1) physical access to an HHS-controlled facility; (2) physical access to an HHS-controlled information system; (3) access to sensitive HHS data or information, whether in an HHS-controlled information system or in hard copy; or (4) any combination of circumstances (1) through (3).
- b. To gain routine physical access to an HHS-controlled information system, and/ or access to sensitive data or information, the Contractor and its employees shall comply

with Homeland Security Presidential Directive (HSPD)-12, Policy for a Common Identification Standard for Federal Employees and Contractors; Office of Management and Budget Memorandum (M-05-24); and Federal Information Processing Standards Publication (FIPS PUB) Number 201; and with the personal identity verification and investigations procedures contained in the following documents:

1. HHS-OCIO Information Systems Security and Privacy Policy ( <http://www.hhs.gov/ocio/policy/#Security>)
2. HHS HSPD-12 Policy Document, v. 2.0 ( <http://www.whitehouse.gov/sites/default/files/omb/assets/omb/memoranda/fy2005/m05-24.pdf>)
3. Information regarding background checks/badges ( <http://idbadge.nih.gov/background/index.asp>)

c. Position Sensitivity Levels:

This contract will entail the following position sensitivity levels:

**Level 6: Public Trust - High Risk.** Contractor/subcontractor employees assigned to Level 6 positions shall undergo a Suitability Determination and Background Investigation (MBI).

**Level 5: Public Trust - Moderate Risk.** Contractor/subcontractor employees assigned to Level 5 positions with no previous investigation and approval shall undergo a Suitability Determination and a Minimum Background Investigation (MBI), or a Limited Background Investigation (LBI).

**Level 1: Non-Sensitive.** Contractor/subcontractor employees assigned to Level 1 positions shall undergo a Suitability Determination and National Check and Inquiry Investigation (NACI).

- d. The personnel investigation procedures for Contractor personnel require that (upon award) the Contractor prepare and submit background check/investigation forms based on the type of investigation required. The minimum Government investigation for a non-sensitive position is a National Agency Check and Inquiries (NACI) with fingerprinting. More restricted positions - i.e., those above non-sensitive, require more extensive documentation and investigation.

As part of its proposal, and if the anticipated position sensitivity levels are specified in paragraph (d) above, the Offeror shall notify the Contracting Officer of (1) its proposed personnel who will be subject to a background check/investigation and (2) whether any of its proposed personnel who will work under the contract have previously been the subject of national agency checks or background investigations.

Upon award, the Contractor shall submit a roster, by name, position, e-mail address, phone number and responsibility, of all staff (including subcontractor staff) working under the contract who will develop, have the ability to access and/or maintain a Federal Information System(s). The roster shall be submitted to the Contracting Officer's Representative (COR), with a copy to the Contracting Officer, within 14 calendar days after the effective date of the contract. The Contracting Officer shall notify the Contractor of the appropriate level of suitability investigations to be performed. An electronic template, "Roster of Employees Requiring Suitability Investigations," is available for contractor use at: [https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/SuitabilityRoster\\_10-15-12.xlsx](https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/SuitabilityRoster_10-15-12.xlsx).

Upon receipt of the Government's notification of applicable Suitability Investigations required, the Contractor shall complete and submit the required forms within 30 days of the notification.

The Contractor shall notify the Contracting Officer in advance when any new personnel, who are subject to a background check/investigation, will work under the contract and if they have previously been the subject of national agency checks or background investigations.

All contractor and subcontractor employees shall comply with the conditions established for their designated position sensitivity level prior to performing any work under this contract.

Contractors may begin work after the fingerprint check has been completed.

- e. Investigations are expensive and may delay performance, regardless of the outcome of the investigation. Delays associated with rejections and consequent re-investigations may not be excusable in accordance with the FAR clause, Excusable Delays - see FAR 52.249-14. Accordingly, the Contractor shall ensure that any additional employees whose names it submits for work under this contract have a reasonable chance for approval.
- f. Typically, the Government investigates personnel at no cost to the Contractor. However, multiple investigations for the same position may, at the Contracting Officer's discretion, justify reduction(s) in the contract price of no more than the cost of the additional investigation(s). Accordingly, if position sensitivity levels are specified in paragraph (d) above, the Offeror shall ensure that the employees it proposes for work under this contract/order have a reasonable chance for approval.
- g. The Contractor shall include language similar to this "HHS Controlled Facilities and Information Systems Security" language in all subcontracts that require subcontractor personnel to have the same frequency and duration of (1) physical access to an HHS-controlled facility; (2) logical access to an HHS-controlled information system; (3) access to sensitive HHS data/information, whether in an HHS-controlled information system or in hard copy; or (4) any combination of circumstances (1) through (3).
- h. The Contractor shall direct inquiries, including requests for forms and assistance, to the Contracting Officer.
- i. Within 7 calendar days after the Government's final acceptance of the work under this contract, or upon termination of the contract, the Contractor shall return all identification badges to the Contracting Officer or designee.

**B. Standard for Encryption Language, HHSAR 352.239-71, (January 2010)**

- a. The Contractor shall use Federal Information processing Standard (FIPS) 140-2-compliant encryption (Security) Requirements for Cryptographic Module, as amended) to protect all instances of HHS sensitive information during storage and transmission. (Note: The Government has determined that HHS information under this contract is considered "sensitive" in accordance with FIPS 199, Standards for Security Categorization of Federal Information and Information Systems, dated February 2004).
- b. The Contractor shall verify that the selected encryption product has been validated under the Cryptographic Module Validation Program (see <http://csrc.nist.gov/cryptval/>) to confirm compliance with FIPS 140-2 (as amended). The Contractor shall provide a written copy of the validation documentation to the Contracting Officer and the Contracting Officer's Technical Representative.
- c. The Contractor shall use the Key Management Key (see FIPS 201, Chapter 4, as amended) on the HHS personal identification verification (PIV) card; or alternatively, the Contractor shall establish and use a key recovery mechanism to ensure the ability for authorized personnel to decrypt and recover all encrypted information (see <http://>

[csrc.nist.gov/drivers/documents/ombencryption-guidance.pdf](http://csrc.nist.gov/drivers/documents/ombencryption-guidance.pdf)). The Contractor shall notify the Contracting Officer and the Contracting Officer's Technical Representative of personnel authorized to decrypt and recover all encrypted information.

- d. The Contractor shall securely generate and manage encryption keys to prevent unauthorized decryption of information in accordance with FIPS 140-2 (as amended).
- e. The Contractor shall ensure that this standard is incorporated into the Contractor's property management/control system or establish a separate procedure to account for all laptop computers, desktop computers, and other mobile devices and portable media that store or process sensitive HHS information.
- f. The Contractor shall ensure that its subcontractors (all tiers) which perform work under this contract comply with the requirements contained in this clause.

**C. Security Requirements For Federal Information Technology Resources, HHSAR 352.239-72, (January 2010)**

- a. **Applicability.** This clause applies whether the entire contract or order (hereafter "contract"), or portion thereof, includes information technology resources or services in which the Contractor has physical or logical (electronic) access to, or operates a Department of Health and Human Services (HHS) system containing, information that directly supports HHS' mission. The term "information technology (IT)", as used in this clause, includes computers, ancillary equipment (including imaging peripherals, input, output, and storage devices necessary for security and surveillance), peripheral equipment designed to be controlled by the central processing unit of a computer, software, firmware and similar procedures, services (including support services) and related resources. This clause does not apply to national security systems as defined in FISMA.
- b. **Contractor responsibilities.** The Contractor is responsible for the following:
  - 1. Protecting Federal information and Federal information systems in order to ensure their -
    - a. Integrity, which means guarding against improper information modification or destruction, and includes ensuring information non-repudiation and authenticity;
    - b. Confidentiality, which means preserving authorized restrictions on access and disclosure, including means for protecting personal privacy and proprietary information; and
    - c. Availability, which means ensuring timely and reliable access to and use of information.
  - 2. Providing security of any Contractor systems, and information contained therein, connected to an HHS network or operated by the Contractor, regardless of location, on behalf of HHS.
  - 3. Adopting, and implementing, at a minimum, the policies, procedures, controls and standards of the HHS Information Security Program to ensure the integrity, confidentiality, and availability of Federal information and Federal information systems for which the Contractor is responsible under this contract or to which it may otherwise have access under this contract. The HHS Information Security Program is outlined in the HHS Information Security Program Policy, which is available on the HHS Office of the Chief Information Officer's (OCIO) Web site.
- c. **Personal identity verification.** The Contractor shall identify its employees with access to systems operated by the Contractor for HHS or connected to HHS systems and networks.

The Contracting Officer's Representative (COR) shall identify, for those identified employees, position sensitivity levels that are commensurate with the responsibilities and risks associated with their assigned positions. The Contractor shall comply with the HSPD-12 requirements contained in "HHS-Controlled Facilities and Information Systems Security" requirements specified in the SOW/PWS of this contract.

- d. **Contractor and subcontractor employee training.** The Contractor shall ensure that its employees, and those of its subcontractors, performing under this contract complete HHS-furnished initial and refresher security and privacy education and awareness training before being granted access to systems operated by the Contractor on behalf of HHS or access to HHS systems and networks. The Contractor shall provide documentation to the COR evidencing that Contractor employees have completed the required training.
- e. **Government access for IT inspection.** The Contractor shall afford the Government access to the Contractor's and subcontractors' facilities, installations, operations, documentation, databases, and personnel used in performance of this contract to the extent required to carry out a program of IT inspection (to include vulnerability testing), investigation, and audit to safeguard against threats and hazards to the integrity, confidentiality, and availability, of HHS data or to the protection of information systems operated on behalf of HHS.
- f. **Subcontracts.** The Contractor shall incorporate the substance of this clause in all subcontracts that require protection of Federal information and Federal information systems as described in paragraph (a) of this clause, including those subcontracts that
  - a. Have physical or electronic access to HHS' computer systems, networks, or IT infrastructure; or
  - b. Use information systems to generate, store, process, or exchange data with HHS or on behalf of HHS, regardless of whether the data resides on a HHS or the Contractor's information system.
- g. **Contractor employment notice.** The Contractor shall immediately notify the Contracting Officer when an employee either begins or terminates employment (or is no longer assigned to the HHS project under this contract), if that employee has, or had, access to HHS information systems or data.
- h. **Document information.** The Contractor shall contact the Contracting Officer for any documents, information, or forms necessary to comply with the requirements of this clause.
- i. **Contractor responsibilities upon physical completion of the contract.** The Contractor shall return all HHS information and IT resources provided to the Contractor during contract performance and certify that all HHS information has been purged from Contractor-owned systems used in contract performance.
- j. **Failure to comply.** Failure on the part of the Contractor or its subcontractors to comply with the terms of this clause shall be grounds for the Contracting Officer to terminate this contract.

(End of Clause)

**Note:** The NIST Special Publication SP-800-26 cited in subparagraph c.1.a.(ii) of this clause has been superseded by NIST SP 800-53A, "Guide for Assessing the Security Controls in Federal Information Systems and Organizations" for use for the assessment of security control effectiveness. See <http://csrc.nist.gov/publications/PubsSPs.html> to access NIST Special Publications (800 Series).

## 1. INFORMATION SECURITY TRAINING

In addition to any training covered under paragraph (e) of HHSAR 352.239-72, the contractor shall comply with the below training:

### a. Mandatory Training

- i. All Contractor employees having access to (1) Federal information or a Federal information system or (2) sensitive data/information as defined at HHSAR 304.1300(a)(4), shall complete the NIH Computer Security Awareness Training course at <http://irtsectraining.nih.gov/> before performing any work under this contract. Thereafter, Contractor employees having access to the information identified above shall complete an annual NIH-specified refresher course during the life of this contract. The Contractor shall also ensure subcontractor compliance with this training requirement.
- ii. The Contractor shall maintain a listing by name and title of each Contractor/Subcontractor employee working on this contract and having access of the kind in paragraph 1.a(1) above, who has completed the NIH required training. Any additional security training completed by the Contractor/Subcontractor staff shall be included on this listing. The list shall be provided to the COR and/or Contracting Officer upon request.

### b. Role-based Training

HHS requires role-based training when responsibilities associated with a given role or position, could, upon execution, have the potential to adversely impact the security posture of one or more HHS systems. Read further guidance about "NIH Information Security Awareness and Training Policy," at: <https://ocio.nih.gov/InfoSecurity/Policy/Documents/Final-InfoSecAwarenessTrainPol.doc>.

The Contractor shall maintain a list of all information security training completed by each contractor/subcontractor employee working under this contract. The list shall be provided to the COR and/or Contracting Officer upon request.

### c. Rules of Behavior

The Contractor shall ensure that all employees, including subcontractor employees, comply with the NIH Information Technology General Rules of Behavior ( <https://ocio.nih.gov/InfoSecurity/training/Pages/nihitrob.aspx>), which are contained in the NIH Information Security Awareness Training Course <http://irtsectraining.nih.gov>.

## 2. PERSONNEL SECURITY RESPONSIBILITIES

In addition to any personnel security responsibilities covered under HHSAR 352.239-72, the contractor shall comply with the below personnel security responsibilities:

- a. In accordance with Paragraph (h) of HHSAR 352.239-72, the Contractor shall notify the Contracting officer and the COR **within five working days** before a new employee assumes a position that requires access to HHS information systems or data, or when an employee with such access stops working on this contract. The Government will initiate a background investigation on new employees assuming a position that requires access to HHS information systems or data, and will stop pending background investigations for employees that no longer work under the contract or no longer have such access.

- b. **New contractor employees who have or will have access to HHS information systems or data:** The Contractor shall provide the COR with the name, position title, e-mail address, and phone number of all new contract employees working under the contract and provide the name, position title and position sensitivity level held by the former incumbent. If an employee is filling a new position, the Contractor shall provide a position description and the Government will determine the appropriate position sensitivity level.
- c. **Departing contractor employees:** The Contractor shall provide the COR with the name, position title, and position sensitivity level held by or pending for departing employees. The Contractor shall perform and document the actions identified in the Contractor Employee Separation Checklist (<https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/Emp-sep-checklist.pdf>) when a Contractor/subcontractor employee terminates work under this contract. All documentation shall be made available to the COR upon request.
- d. **Commitment to Protect Non-Public Departmental Information and Data.**

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

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

Each employee, including subcontractors, having access to non- public Department information under this acquisition shall complete the "Commitment to Protect Non-Public Information - Contractor Employee Agreement" located at: <https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/Nondisclosure.pdf>. A copy of each signed and witnessed Non-Disclosure agreement shall be submitted to the Project Officer/COR prior to performing any work under this acquisition.

#### 14. **Solicitation Provisions Incorporated by Reference, FAR 52.252-1 (February 1998)**

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

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

- a. Central Contractor Registration, FAR Provision 52.204-7 (December 2012), **Alternate I** (December 2012) is not applicable to this solicitation.
- b. Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8, (October 1997).
- c. Limitations on Pass-Through Charges--Identification of Subcontract Effort, FAR Provision 52.215-22, (October 2009).
- d. Identification of Uncompensated Overtime, FAR Clause 52.237-10, (October 1997).

## b. TECHNICAL PROPOSAL INSTRUCTIONS

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

There are no page limits for the technical proposal. Offerors are urged to be as concise as possible while providing the necessary level of detail to allow for a fair evaluation of its capabilities and experience.

**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 all 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.**

The following information shall be provided by the offeror for all staff/individuals who are proposed for direct performance of work under any resultant contract, e.g., Stroke Medical Director (Principal Investigator), other physician support, nurse coordinator, MRI technologist support, pharmacist, administrative support, etc. **In addition, the offeror shall provide a separate "Summary of Related Activities" form, (See Section J, Attachment #4) for each key professional individual proposed for work under the project.**

1. Stroke Medical Director/Principal Investigator  
List the name of the Stroke Medical Director/Principal Investigator who will be responsible for overall implementation of the contract and key contact for technical aspects of the project. Discuss the qualifications, experience, and accomplishments of this individual. 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/Professional Personnel  
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 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 as described in paragraph 11, Selection of Offerors under Section A above, using the technical evaluation criteria outlined in Section M - Evaluation Factors for Award of this solicitation.

## 4. Human Subjects

**IMPORTANT NOTE TO OFFERORS: The following subparagraphs a, b, and c, shall be addressed, as applicable, in a SEPARATE SECTION of the Technical Proposal entitled, "HUMAN SUBJECTS." In addition, institutions having an OHRP-approved FWA shall provide evidence of IRB approval of the proposal by submission of [OMB Form No. 0990-0263](#), "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption (Common Rule); or by letter indicating the institution's OHRP-assigned FWA number, the date of IRB review and approval, and the type of review (convened or expedited). This form is provided as Attachment #5 under Section J.**

### a. Notice to Offerors of Requirements of 45 CFR Part 46, Protection of Human Subjects, HHSAR 352.270-4(a) (January 2006)

- 1) Copies of the Department of Health and Human Services (HHS) regulations for the protection of human subjects, 45 CFR Part 46, are available from the Office for Human Research Protections (OHRP), Bethesda, Maryland 20892. The regulations provide a systematic means, based on established ethical principles, to safeguard the rights and welfare of individuals who participate as subjects in research activities supported or conducted by the HHS.
- 2) The regulations define a human subject as a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information. The regulations extend to the use of human organs, tissue, and body fluids from individually identifiable human subjects as well as to graphic, written, or recorded information derived from individually identifiable human subjects. The use of autopsy materials is governed by applicable State and local law and is not directly regulated by 45 CFR Part 46.
- 3) Activities in which the only involvement of human subjects will be in one or more of the categories set forth in 45 CFR 46.101(b)(1-6) are exempt from coverage.
- 4) Inappropriate designations of the noninvolvement of human subjects or of exempt categories of research in a project may result in delays in the review of a proposal. The Government's Project Officer will make a final determination of whether the proposed

activities are covered by the regulations or are in an exempt category, based on the information provided in the proposal. In doubtful cases, the Project Officer will consult with OHRP.

- 5) In accordance with 45 CFR Part 46, prospective Contractors being considered for award shall be required to file with OHRP an acceptable Assurance of Compliance with the regulations, specifying review procedures and assigning responsibilities for the protection of human subjects. The initial and continuing review of a research project by an institutional review board shall assure that: the rights and welfare of the human subjects involved are adequately protected; the risks to the subjects are reasonable in relation to both the potential benefits, if any, to the subjects and the importance of the knowledge to be gained; and informed consent will be obtained by methods that are adequate and appropriate. HHS regulations for the protection of human subjects (45 CFR Part 46), information regarding OHRP registration and assurance requirements/ processes, and OHRP contact information can be accessed at the OHRP Web site (at <http://www.hhs.gov/ohrp/>).
- 6) Offerors may consult with OHRP for advice or guidance concerning either regulatory requirements or ethical issues pertaining to research involving human subjects.

(End of provision)

#### **b. Instructions to Offerors Regarding Protection of Human Subjects**

Offerors must address the following human subjects protections issues in their proposal:

##### 1) Risks to the subjects

- Human Subjects Involvement and Characteristics:
  - Describe the proposed involvement of human subjects in response to the solicitation.
  - Describe the characteristics of the subject population, including their anticipated number, age range, and health status.

##### 2) Adequacy of Protection Against Risks

###### i. Recruitment and Informed Consent:

1. Describe plans for the recruitment of subjects and the procedures for obtaining informed consent. Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent.

###### ii. Protection Against Risk:

1. Describe the procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness.
2. Discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects where appropriate.

#### **c. Required Education in the Protection of Human Research Participants**

NIH policy requires education on the protection of human subject participants for all investigators submitting NIH proposals for contracts for research involving human subjects. This policy announcement is found in the [NIH Guide for Grants and Contracts](#) Announcement

dated June 5, 2000 at the following website: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>. Offerors should review the policy announcement prior to submission of their offers. The following is a summary of the Policy Announcement:

For any solicitation for research involving human subjects, the offeror shall provide in its technical proposal the following information: (1) a list of the names of the principal investigator and any other individuals proposed under the contract who are responsible for the design and/or conduct of the research; (2) the title of the education program completed (or to be completed prior to the award of the contract) for each named personnel; (3) a one sentence description of the program(s) listed in (2) above. This requirement extends to investigators and all individuals responsible for the design and/or conduct of the research who are working as subcontractors or consultants under the contract.

Curricula that are readily available and meet the educational requirement include the NIH Office of Extramural Research (OER) on-line tutorial, entitled "Protecting Human Research Participants" at: <http://phrp.nihtraining.com>. This course is also available in Spanish under the title "Protección de los participantes humanos de la investigación" at: <http://pphi.nihtraining.com>. You may take the tutorials on-line or download the information in PDF form at no cost. The University of Rochester has made its training program available for individual investigators. Completion of this program will also satisfy the educational requirement. The University of Rochester manual, entitled, "Protecting Study Volunteers in Research," can be obtained through Centerwatch, Inc. at: <http://store.centerwatch.com/c-29-training-guides.aspx>.

If an institution already has developed educational programs on the protection of research participants, completion of these programs also will satisfy the educational requirement.

In addition, prior to the substitution of the principal investigator or any other individuals responsible for the design and/or conduct of the research under the contract, the Contractor shall provide the contracting officer with the title of the education program and a one sentence description of the program that the replacement has completed.

5. **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/quotation/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 – Attachment No. 6 of this solicitation.**

## **c. BUSINESS PROPOSAL INSTRUCTIONS**

### **1. Budget Structure**

Offerors shall provide a budget summary page for the overall project, which will include the base contract and each possible term option using the "Total Cost Summary - Business Proposal Budget Template," provided as Attachment No. 7 under Section J.

In addition to the Total Cost Summary – Business Proposal Budget Template, offerors shall prepare individual budgets for the base contract year and for each possible option term year. The individual budgets must itemize cost for all costs type categories, e.g., labor, fringe benefits, and materials, overhead, etc. estimated to be incurred in direct performance of work under the proposed contract. All costs shall be supported by narrative justification and supporting cost documentation.

**NOTE:** Please submit all budgets, including the Total Cost Summary, and individual itemized budget sheets on a CD in Microsoft Excel® format.

### **2. Basic Cost/Price Information**

The business proposal must contain sufficient information to allow the Government to perform a basic cost realism analysis of the proposed cost or price of the work. This information shall include payroll documentation, vendor quotes, invoice prices and/or any other information deemed necessary to evaluate the reasonableness of the price or to determine cost realism for all

of the proposed cost elements. These elements include, as applicable, direct labor, fringe benefits, travel, materials, subcontracts, purchased parts, shipping, indirect costs and rate, and if applicable, fee, and profit.

### 3. **Proposal Cover Sheet**

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

- i. Solicitation, contract, and/or modification number;
- ii. Name and address of Offeror;
- iii. Name and telephone number of point of contact;
- iv. Name, address, and telephone number of Contract Administration Office, (if available);
- v. Name, address, and telephone number of Audit Office (if available);
- vi. Proposed cost and/or price; profit or fee (as applicable); and total;
- vii. 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.
- viii. Date of submission; and
- ix. 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.

### 4. **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.

#### 1. **Direct Labor**

Identify and provide a breakdown, by individual or labor class, the labor effort/hours and rates for all personnel who will be directly involved in work under the project. Provide a written narrative justifying the basis of the labor effort proposed for all personnel/positions.

#### 2. **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.

**3. Materials/Supplies**

Provide a summary listing and/or bill of materials for all individual material and supply item types and quantities and the basis for the line item cost/pricing estimate. This information should be supported with documentation such as current vendor quotes, invoices based on recent purchases, catalog price lists/schedules, etc.

**4. Subcontracted Items**

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

**5. 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.

**6. Travel**

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

**7. 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.

**8. Indirect Costs**

Indicate how offeror has computed and applied proposed 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.

**5. Requirements for Certified Cost or Pricing Data and Data Other than Certified Cost or Pricing Data, FAR Clause 52.215-20 (October 2010)**

(a) Exceptions from certified cost or pricing data.

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

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

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

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

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

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

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

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

(1) The offeror shall prepare and submit certified cost or pricing data, data other than certified cost or pricing data, and supporting attachments in accordance with the instructions contained in Table 15-2 of FAR 15.408, which is incorporated by reference with the same force and effect as though it were inserted here in full text. The instructions in Table 15-2 are incorporated as a mandatory format to be used in this contract, unless the Contracting Officer and the Contractor agree to a different format and change this clause to use Alternate I.

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

(End of provision)

## 6. Salary Rate Limitation in Fiscal Year 2014

Offerors are advised that pursuant to P.L. 113-76, no NIH Fiscal Year 2013 (October 1, 2013 - September 30, 2014) 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 salary rate limitation set by P.L. 113-76 applies only to Fiscal Year 2014 funds, however, salary rate ceilings for subsequent years may be included in future DHHS appropriation acts. Multi-year contracts awarded pursuant to this solicitation

may be subject to unilateral modifications by the Government if an individual's annual salary exceeds any salary rate ceiling established in future appropriations acts. The Executive Schedule, Level II\* annual salary rate limitation also applies to individuals proposed under subcontracts, however it does not apply to consultants. P.L. 113-76 states:

"None of the funds appropriated in this title shall be used to pay the salary of an individual through a grant or other extramural mechanism, at a rate in excess of Executive Level II."

**LINK TO EXECUTIVE SCHEDULE RATES OF PAY:** <http://www.opm.gov/oca/>

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

**\*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.

#### 7. **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 ATTACHMENT No. 8 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.

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

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

(End of provision)

#### 9. **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>.

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

In accordance with FAR Subpart 15.304(c)(4), the extent of participation of Small Disadvantaged Business (SDB) concerns in performance of the contract in the authorized NAICS Industry Subsectors shall be evaluated in unrestricted competitive acquisitions expected to exceed \$650,000 (\$1.5 million for construction) subject to certain limitations (see FAR 19.1202-1 and

19.1202-2(b). The dollar amounts cited above include any option years/option quantities that may be included in this solicitation. The definition of a "small disadvantaged business" is cited in FAR 19.001.

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

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

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

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

Offerors shall include with their offers, SDB participation targets, expressed as dollars and percentages of total contract value, in each of the applicable, authorized NAICS Industry Subsector(s). The applicable authorized NAICS Industry Subsector(s) for this project is 622110. A total target for SDB participation by the Prime Contractor, that includes any joint ventures and team members, shall be provided as well as a total target for SDB participation by subcontractors. In addition, offerors must provide information that describes their plans for meeting the targets set forth in their proposal. **SDB Participation Plan information may be provided by using Attachment 10, entitled "SDB Participation Factor" or in a format developed by the offeror. This information shall be provided in one clearly marked section of the Business Proposal, which shall describe the extent of participation of SDB concerns in the performance of the contract.**

Offerors should note that addressing the extent of small disadvantaged business participation is **not in any way intended to be a substitute** for submission of the subcontracting plan, if it is required by this solicitation. An example of the type of information that might be given (in addition to the narrative describing the plan for meeting the targets) follows:

EXAMPLE

Targets for SDB Participation - NAICS Industry Subsector 223

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

\*Note: FAR Subpart 9.6 defines "Contractor team arrangements" to include two or more companies forming a partnership or joint venture to act as a potential Prime Contractor, or a potential Prime Contractor who agrees with one or more companies to have them act as its subcontractors on a specific contract or acquisition program. For purposes of evaluation of the SDB participation factor,

FAR 19.1202-4 requires that SDB joint ventures and teaming arrangements at the prime level be presented separately from SDB participation by subcontractors.

## 11. 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.

### 3. Government-Furnished Property

A Listing of Government Furnished Property, Schedule II-B, is provided in Article G.5 - Government Property of this solicitation.

4. The management and control of any Government property shall be in accordance with the HHS Publication entitled, "HHS Contracting Guide for Contract of Government Property," which can be found at: [http://www.hhs.gov/hhsmanuals/logisticsmanual/Appendix Q\\_HHS Contracting Guide.pdf](http://www.hhs.gov/hhsmanuals/logisticsmanual/Appendix_Q_HHS_Contracting_Guide.pdf)

### 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 clauses concerning limitation of cost (FAR 52.232-20 and 21) 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.

(End of provision)

## 12. 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.

**13. Subcontractors**

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

- a. Willingness to perform as a subcontractor for specific duties (list duties).
- b. What priority the work will be given and how it will relate to other work.
- c. The amount of time and facilities available to this project.
- d. Information on their cognizant field audit offices.
- e. How rights to publications and patents are to be handled.
- f. A complete cost proposal in the same format as the offeror's cost proposal.

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

<http://ocm.od.nih.gov/contracts/rfps/FDP/FDPclausecover.htm>

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

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

**15. Travel Costs/Travel Policy**

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

## SECTION M - EVALUATION FACTORS FOR AWARD

### A. General Information Regarding Evaluation Factors for Award

Selection of an offeror(s) for contract award will be based on an evaluation of proposals against the following factors. These factors include a mandatory qualification criteria, technical evaluation criteria, past performance, cost/price, and Small Disadvantaged Business (SDB) Participation factors. All evaluation factors, other than cost /price, when combined, are more important than cost/price. However, cost/price may become a critical factor in source selection in the event that two or more offerors are determined to be essentially equal following the evaluation of all factors other than cost or price. The Government intends to make an award(s) to the offeror(s) whose proposal provides the best overall value to the Government. The trade-off process described in FAR 15.101-1 may be employed in order to determine best value.

Evaluation of an offeror's proposal will consider the demonstrated capabilities of the offeror in relation to the needs of the project as set forth in this SOLICITATION. The merits of each proposal will be evaluated carefully. Each proposal must document the feasibility of successful implementation of the requirements of this SOLICITATION. Offerors must submit all necessary information to allow for a full and complete evaluation of their proposal based on the factors listed below.

### B. Evaluation of Options

It is anticipated that any contract(s) awarded from this solicitation will contain additional option periods.

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 base contract, 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).

### C. Mandatory Qualification Criteria

Listed below are mandatory qualification criteria. The mandatory qualification criteria establishes conditions that must be met at the time of receipt of the offeror's proposal in response to this solicitation in order for your proposal to be considered any further for award.

THE OFFEROR SHALL INCLUDE ALL INFORMATION WHICH DOCUMENTS AND/OR SUPPORTS EACH MANDATORY QUALIFICATION CRITERIA BELOW IN ONE CLEARLY MARKED SECTION OF THEIR TECHNICAL PROPOSAL.

1. **Location of Contractor:** Contractor must be located within 15 miles of the NIH Campus (9000 Rockville Pike, Bethesda, MD 20892). Since the goal of this program is to evaluate acutely ill patients, the proximity of the hospital to NIH is critical to permit clinical and scientific staff the ability to travel quickly from NIH to Contractor's site to manage the care these patients.
2. **Certification:** Hospital shall have achieved Primary Stroke Center Certification or Comprehensive Stroke Center Certification by The Joint Commission and, for hospitals in Maryland, the additional certification as Primary Stroke Center by the Maryland Institute for Emergency Medicine Services Systems (MIEMSS) Stroke Designation.

### D. Technical Evaluation

An initial technical review will be conducted to evaluate technical proposals against the technical evaluation criteria specified below, which are weighted in the order of their relative importance. The maximum total score possible is 100 points.

**Offerors are advised and cautioned that proposals will be evaluated solely on the information provided in their proposal.**

Offerors must address all aspects of the Statement of Work and submit sufficient information to allow evaluation of their proposal against the Technical Evaluation Criteria listed below. Failure to provide any of the information required

by the RFP will result in a less than favorable evaluation of your proposal.

## Technical Evaluation Criteria

### 1. Technical Approach/Capabilities. (0-50 points)

- The adequacy of the offeror's overall approach and ability to perform and execute all aspects of the Statement of Work. (0-15)
- The adequacy of the offeror's approach and ability to identify and refer patients from the acute stroke and traumatic brain injury patients evaluated at their hospital to the research protocols of the NIH Team. (0-15)
- The quality of the offeror's existing state-of-the-art MRI facility with advanced brain MR imaging capabilities. The facilities' location in close proximity (5 minutes or less) to Emergency Room with scanning availability for acute stroke patients within 15 minutes of notification and MRI technologist coverage of facility 24 hours a day, 7 days a week. (0-10)
- Adequacy of offeror's plan to assign existing staff and ability and approach to recruit and hire new staff, if not already in place, for the contract. (0-10)

### 2. Personnel (0-35 points)

- The specific experience, education, training, availability, and level of effort of staff proposed to directly support work under the contract and the NIH Team to include the proposed PI, Stroke Medical Director, and dedicated nurse coordinator. (0-25)
- The adequacy and availability of ancillary support staff/teams (e.g., physicians, vascular neurologist, MRI technologists, nurses, radiologists, interventional radiologists, etc) providing the clinical care of the acute stroke patients followed by the NIH Team. (0-10)

### 3. Organizational, Clinical and Administrative Infrastructure Commitment (0-15 points)

The extent and adequacy of the offeror's proposed organizational, clinical, and administrative infrastructure commitment for supporting the NIH Team. This shall include an evaluation of the hospital's organization and commitment to supporting the NIH Team and work under the contract, prior experience conducting acute clinical trials, the commitment of the hospital administration to facilitate an acceptable and adequate collaboration between hospital departments and the NIH Team, and recognition of the priority of the protocols approved by the NIH and contractor institutional review boards. Acute care services, dedicated patient beds for stroke patients, other diagnostic facilities and equipment, and necessary office space to support the needs of the NIH Team.

## E. Past Performance

An evaluation of an offeror's past performance information will be conducted prior to any communications with offerors leading to establishment of the competitive range.

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

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

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

When assessing performance risks, the Government will focus on the past performance of the offeror as it relates to all acquisition requirements, such as, the offeror's record of performing according to specifications, including standards of

good workmanship; the offeror's record of controlling and forecasting costs; the offeror's adherence to contract schedules, including the administrative aspects of performance; the offeror's reputation for reasonable and cooperative behavior and commitment to customer satisfaction; and generally, the offeror's business-like concern for the interest of the customer.

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

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

## **F. Cost/Price Evaluation**

Proposals received in response to this solicitation shall be subjected to several forms of proposal analysis techniques to assure that the final agreed to price is fair and reasonable. Proposals will be subjected to a price analysis whereby a comparison will be made of proposed prices received from all offerors responding to the solicitation. 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.

In addition, a cost realism analysis shall also be performed on each proposal pursuant to FAR 15.404-1(d). Cost realism analysis is the process of independently reviewing and evaluating specific elements of each offeror's proposed cost estimate to determine whether the estimated proposed cost elements are realistic for the work to be performed; reflect a clear understanding of the requirements; and are consistent with the approach and methods of performance and resources described in the offeror's technical proposal.

The results of our price analysis and cost realism analysis will be considered in making a best-value source selection decision.

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

In accordance with FAR Part 15.304(c) 4, the extent of participation of Small Disadvantaged Business (SDB) concerns in performance of the contract shall be evaluated and scored independent of the technical merit review. Offerors shall submit information on planned SDB participation in one clearly marked section of your business proposal. Please note that the SDB Participation Factor is separate from the requirement to provide a Small Business Subcontracting Plan. The SDB Participation Factor describes the extent of participation of SDB concerns in performance of the contract. This can include joint ventures, teaming arrangements, subcontracts and participation in performance of the contract expected to be performed by SDB concerns at the prime contract level.

Evaluation of the SDB Participation Factor will be assessed based on consideration of the information presented in the offeror's proposal. We request that offeror's provide the "Participation Factor" information on the attached form "Small Disadvantaged Business (SDB) Participation Factor", see Attachment No.10 to the solicitation. The Government is seeking to determine whether the offeror has demonstrated a commitment to use SDB concerns for the work that it intends to perform.

The offeror's SDB Participation Factor will be evaluated by the following two sub-factors:

- 1) Extent of commitment to use SDB concerns in performance of the contract (in terms of dollars and percentage of total contract value; and
- 2) The complexity and variety of work to be performed by SDB concerns.

The offeror's Small Disadvantaged Business Participation Factor will be evaluated before determination of the competitive range.

## **H. OTHER NON-SCORED FACTORS**

### **1. 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" and provided as Attachment No. 6 under Section J) 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.

## **2. Human Subjects Evaluation**

This project involves human subjects. NIH Policy requires:

The offeror's proposal must address the involvement of human subjects and protections from research risk relating to their participation, or provide sufficient information on the research subjects to allow a determination by the NINDS that a designated exemption is appropriate.

If you claim that this research should be considered exempt from coverage by the Federal Regulations at 45 CFR 46, the proposal should address why you believe it is exempt, and under which exemption it applies.

The reviewers will evaluate the proposal with regard to two issues: Risks to Human Subjects and Adequacy of Protection Against Risks. See Section L of the solicitation for a complete discussion of what is required to be addressed in your technical proposal for each of these issues. Based on your response to this criterion, this section of your proposal may be rated "acceptable" or "unacceptable" (i.e., concerns are identified as to the protections described against risk to human subjects or no discussion is found regarding protections against risk to human subjects)." If the reviewers find that this portion of the proposal is "unacceptable" they will provide a narrative supporting their finding.

If the Government includes your proposal in the competitive range, you will be afforded the opportunity to address the concerns raised by the reviewers. You will be able to further discuss and/or clarify your position until submission of your Final Proposal Revision (FPR). Once discussions are closed with the submission of your FPR, if your proposed plan for the protection of human subjects from research risks is still found to be unacceptable, then it may not be considered further for award.