

Request for Proposal (RFP) No. N01DA-10-7773
“Production, Analysis, and Distribution of Cannabis, Marijuana Cigarettes, and Related Materials”

Issued by:

Kenneth E. Goodling Contracting Officer
NIDA R & D Contracts Management Branch
Neuroscience Office of Acquisitions
National Institute on Drug Abuse, NIH
6101 Executive Boulevard
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Bethesda, MD 20892-8402

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DATE ISSUED: August 28, 2009

PROPOSAL DUE DATE: October 13, 2009, 3:00 P.M. (local time)

Ladies and Gentlemen:

The National Institute on Drug Abuse invites you to send a proposal responding to the requirements of this RFP No. N01DA-10-7773 for “Production, Analysis, and Distribution of Cannabis, Marijuana Cigarettes, and Related Materials.”

This Request for Proposal is prepared in accordance with the Uniform Contract Format prescribed for Government Wide application by the Federal Acquisition Regulation (FAR). The Uniform Contract Format is both a Request for Proposal and a contract award document. The resulting contract will consist of Parts I, II, III of the Uniform Contract Format.

A Cost Reimbursement, Level of Effort contract is contemplated for a base period of 1 year with potential for 4 option years. Additional quantity options are also included. Any contract resulting from this Request for Proposal will be fully funded for the base contract; options will be funded dependent on the previous year's performance and the availability of funds. It is anticipated that the base performance period of the contract will be from March 2010 through March 2011. You are expected to respond with technical and pricing proposals for the entire project and total period of performance, including separately priced option years and quantities.

Your attention is particularly directed to Part IV, which contains instructions, provisions, and evaluation factors for the submission and review of proposals. Your attention is further directed to Attachment 2, "Proposal Intent Response Sheet." Please complete this form and return it to this office on or before September 11, 2009. The balance of Parts I, II, and III contain provisions, clauses, and special requirements which will be made a part of any resultant award and therefore should be reviewed by you as to the effects on performance capability and technical and cost considerations in the development of your proposal. However, you do not fill in blanks or otherwise complete portions of Parts I, II, and III which otherwise appear to require the insertion of data. The Government will complete those Parts prior to contract award. Parts I, II, and III will be tailored to the final negotiation with the selected offeror and modified, as necessary, for the

type of contractor organization, cost and/or fee arrangement, and other elements as negotiated prior to award.

The proposal shall be signed by an official authorized to bind your organization. One (1) original and ten (10) copies of your technical proposal and one (1) original and five (5) copies of your business proposal must be received by the Contracting Officer no later than 3:00 p.m., local prevailing time on October 13, 2009 at:

National Institute on Drug Abuse, NIH
NIDA R & D Contracts Management Branch
Neurosciences Office of Acquisitions
6101 Executive Boulevard, Rm 260
Rockville, Maryland 20852

Attn: Amy Sheib, Contract Specialist
RFP No. N01DA-10-7773

Questions concerning any areas of uncertainty, which, in your opinion, require clarification or correction, must be furnished in writing (by e-mail is acceptable) to the Contracting Officer. Your questions must be mailed in sufficient time to be received on or before September 11, 2009. The envelope or e-mail should be marked "Offeror's Questions, RFP No. N01DA-10-7773."

Following your proposal submission and our review, the Contracting Officer may seek more information. In accordance with FAR 15.306(a)(3) and FAR 52.215-1, we advise you that the Government intends to evaluate proposals and award a contract without discussions (except clarifications). Therefore, your initial proposal should contain the best terms from cost or price and technical standpoints. However, we reserve the right to conduct discussions if the Contracting Officer later decides them to be necessary.

You must have an authorized organizational official sign your Business Proposal. It must contain a detailed breakdown of costs by year and individual options, for each cost category/element, an explanation of the basis for all costs, and provide documentation to support these costs. We direct special attention to the COST PROPOSAL SPREADSHEET contained in the Section B. Please provide a hard copy of the spreadsheet in this format and include the electronic file on a CD. Do not send encrypted files. Use of the above format will hasten review and award. See Section L.2.c. Business Proposal Instructions for additional detail.

We advise you that the proposed/negotiated funding amounts for performance during following years of the contract, may not exceed the total proposed/negotiated amount for year one. **(For example, if year one's funding is \$500,000, each following year may not exceed \$500,000.) Offerors must offset potentially higher annual costs for salary increases and escalation by cost savings achieved by economies and efficiencies reached through performance over the life of the contract.**

Please include a completed Form NIH-2043, "Proposal Summary and Data Record" with the Business Proposal. Note that in addition to telephone and fax numbers, you should include the e-mail addresses of both the Principal Investigator and the responsible business representative on the form. The offeror's Small Business Subcontracting Plan, Travel Policy, and Annual report (including financials) also shall be submitted with the initial Business Proposal. Format and content requirements of your Technical Proposal are detailed in Section L.2.b. Technical Proposal. Also, you should complete the "Technical Proposal Cover Sheet" and use it as the cover sheet for each copy of your technical proposal. It is important that you list all professional personnel and organizations named in the proposal that have any role in the proposed work. This includes your staff, subcontractors, collaborating organizations, and consultants. Show organization affiliation(s) for every person named. You may use extra sheets, as needed,

following the format shown in the Technical Proposal Cover Sheet. We will use this information to ensure that no conflicts of interest exist with the selected review committee members.

If you want to receive an e-mail notice of any amendments to this RFP, you should register on the FedBizOpps website. Also, NIDA will post all amendments, or provide an appropriate link, on the NIDA Contracts Home Page.

Any contract award for this requirement will be contingent on the availability of funds (See FAR 52.232-18, AVAILABILITY OF FUNDS – APRIL 1984). **This RFP does not commit the Government to pay the costs for you to prepare and send a proposal. The Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds on any resulting contract.**

Requests for any information concerning this RFP should be directed to Amy Sheib, NIDA R&D Contracts Management Branch, who may be reached on (301) 443-6677; collect calls will not be accepted. **Discussions with any other individual outside the NIDA R&D Contracts Management Branch should not occur.**

Sincerely yours,



Kenneth E. Goodling, Contracting Officer
NIDA R & D Contracts Management Branch
Neurosciences Office of Acquisitions, NIDA/NIH

Enclosure (s)

SOLICITATION

SECTION A - SOLICITATION/CONTRACT FORM

| | | |
|---|---|---|
| 1. Purchase Authority: Public Law 92-218 as amended | | |
| 2. Request for Proposal (RFP) Number: N01DA-10-7773 | 3. Issue Date: August 28, 2009 | 4. Set Aside: <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes See Part IV Section L |
| 5. Title : Production, Analysis, and Distribution of Cannabis, Marijuana Cigarettes, and Related Materials | | |
| 6. ISSUED BY: NIDA R&D Contracts Management Branch Neurosciences Office of Acquisitions, NIH 6101 Executive Blvd., Rm. 260, MSC 8402 Bethesda, MD 20892-8402 Fed-Ex/Hand Delivery use: Rockville, MD 20852 | 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 3:00 p.m. local time on October 13, 2009. Offers will be valid for 120 days unless a different period is specified by the offeror on the Attachment entitled, "Proposal Summary and Data Record, NIH 2043. | | |
| 9. THE OFFICIAL POINT OF RECEIPT FOR THE PURPOSE OF DETERMINING TIMELY DELIVERY IS THE ADDRESS PROVIDED FOR THE OFFICE OF ACQUISITIONS AS STATED IN ATTACHMENT 1, "PACKAGING AND DELIVERY OF THE PROPOSAL." IF YOUR PROPOSAL IS NOT RECEIVED BY THE CONTRACTING OFFICER OR HIS DESIGNEE AT THE PLACE AND TIME SPECIFIED FOR THE OFFICE OF ACQUISITIONS, THEN IT WILL BE CONSIDERED LATE AND HANDLED IN ACCORDANCE WITH HHSAR CLAUSE 352.215-70, ENTITLED, "LATE PROPOSALS, AND REVISIONS" 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. http://www.ccr.gov | | |
| 11. FOR INFORMATION CALL: Amy Sheib PHONE: 301-443-6677 e-MAIL: ap370t@nih.gov COLLECT CALLS WILL NOT BE ACCEPTED. | | |
| | | Kenneth E. Goodling Contracting Officer NIDA R&D Contracts Management Branch Neurosciences Office of Acquisition |

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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, AS NECESSARY, AND WILL BE INCLUDED IN THE RESULTANT CONTRACT. THE ENCLOSED CONTRACT SCHEDULE IS INTENDED TO PROVIDE THE OFFEROR WITH THE NECESSARY INFORMATION TO UNDERSTAND THE TERMS AND CONDITIONS OF THE RESULTANT CONTRACT.

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

This contract shall provide for the production, analysis and distribution of cannabis and marijuana cigarettes. Cannabis is used in a large variety of research projects supported by the National Institute on Drug Abuse and this contract serves as the only source of such material in the United States. Cannabis shall be grown as necessary, followed by careful quantitative analysis and storage prior to shipment to researchers in this country and abroad.

In addition to analysis of grown material, analyses shall be performed on approximately 100 to 150 samples of confiscated marijuana each month which are provided by the Drug Enforcement Administration (DEA). These analyses provide a means of determining potency trends of illicit marijuana by determination of the tetrahydrocannabinol (THC) concentrations and also of screening for herbicide contamination which might create a public health problem.

ARTICLE B.2. ESTIMATED COST

The estimated cost of this contract is \$_____.

ARTICLE B.3. OPTION PRICING

- a. Unless the Government exercises its option pursuant to the option clause referenced in ARTICLE I.3. **ADDITIONAL CONTRACT CLAUSES**, this contract consists only of the Base Period specified in the Statement of Work as defined in SECTIONS C and F, for the estimated cost set forth in ARTICLE B.2. of this contract.
- b. Pursuant to FAR Clause 52.217-7 Option for Increased Quantity - Separately Priced Line Item and FAR Clause 52.217-9 Option to Extend set forth in ARTICLE I.3. **ADDITIONAL CONTRACT CLAUSES** of this contract, the Government may, by unilateral contract modification, require the Contractor to perform the Option Period(s) and/or quantities specified in the Statement of Work as defined in SECTIONS C and F of this contract. If the Government exercises these option(s), notice must be given before the expiration date of the contract. Specific information regarding the time frame for this notice is set forth in the **OPTION PROVISION** Article in SECTION H of this contract. The estimated cost of this contract will be increased as set forth in paragraph c., below.
- c. Upon the delivery and acceptance of the Option Items described in SECTION C of the contract and identified in the schedule of charges below, the Government shall reimburse the Contractor up to the estimated cost for each options set forth below:

| | Year 1 | Option Year 2 | Option Year 3 | Option Year 4 | Option Year 5 |
|---------------------------------|--------|---------------|---------------|---------------|---------------|
| Growing | | | | | |
| Option 1a (1.5 acres) | | | | | |
| Option 1b (6.5 acres) | | | | | |
| Manufacturing | | | | | |
| Option 2a (5,000 placebo) | | | | | |
| Option 2b (15,000 low THC) | | | | | |
| Option 2c (15,000 Medium THC) | | | | | |
| Option 2d (15,000 high THC) | | | | | |
| Option 2e (1,000 very high THC) | | | | | |
| Other | | | | | |
| Option 3 (Transition) | | | | | |
| Option 4 (Option Years) | N/A | | | | |

ARTICLE B.4. PROVISIONS APPLICABLE TO DIRECT COSTS

This article will prohibit or restrict the use of contract funds, unless otherwise approved by the Contracting Officer. The following is a list of items that may be included in the resultant contract as applicable. 1) Acquisition, by purchase or lease, of any interest in real property; 2) Special rearrangement or alteration of facilities; 3) Purchase or lease of any item of general purpose office furniture or office equipment regardless of dollar value; 4) Travel Costs; 5) Consultant Costs; 6) Subcontract Costs; 7) Patient Care Costs; 8) Accountable Government Property; 9) Research Funding; and 10) Food Costs.

ARTICLE B.5. ADVANCE UNDERSTANDINGS

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

SECTION C - WORK STATEMENT

ARTICLE C.1. STATEMENT OF WORK

- a. Independently and not as an agent of the Government, the Contractor shall furnish all necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government as needed to perform the Statement of Work:

I. Background information and Objectives

A. Background Information

The primary function of this contract is to provide materials to support research on marijuana abuse, its effects on psychological and physical development, driving ability, medical use and consequences, and on human health in general. It was recognized long ago that such studies require a source of cannabis materials with consistent and predictable potency, free of contamination and in sufficient amounts to support a wide variety of research needs. Such production was established in the late 1960's by the federal government. Formulation of marijuana as cigarettes was also necessitated due to the federal government's marijuana compassionate program and research on effects of smoked marijuana on health. This present procurement is a continuation of that effort. The production and distribution of cannabis and marijuana require frequent analyses of growing and stored materials to determine their optimum harvesting time and potency stability.

Several years ago, the NIDA was asked by the United States Congress to initiate a collaborative relationship with the DEA to monitor the potency of illicit marijuana. This highly successful program provided NIDA, DEA and other interested Federal agencies with a comprehensive base of information on the potency of marijuana in respect to the time (1973 present), geographical area of confiscation, type of marijuana (loose leaf, brick, Thai stick, and sinsemilla, etc), and many other factors useful to DEA and NIDA in assessing illicit distribution patterns and potential public health impact. In 1977 when herbicides were beginning to be used to eradicate marijuana fields in Mexico with the assistance of the US., a public controversy arose concerning the issue of whether such action could lead to a new public health problem where the toxic effects of the burned herbicide might exacerbate the toxic effects of marijuana smoke on the lung. NIDA was asked by the White House to assist in providing information to allow an appropriate assessment of such risk. Such information consisted in part of data on the screening of the DEA confiscated samples for traces of herbicides. This concern is still continuing with the current policies on herbicide eradication of marijuana in the US. and South America. The screening presently being done in conjunction with the DEA potency monitoring program, is an integral part of the Assistant Secretary's congressionally mandated alert system for assessing public health impact of such contamination.

Cannabis and marijuana cigarettes are not available through commercial or any other legal sources. Similarly chemical constituents of marijuana, such delta-9-tetrahydrocannabinol (THC) and other cannabinoids are not available commercially in sufficient quantities for research. They are classified as Schedule I substances under the Controlled Substance Act. The NIDA has been providing the scientific community with standardized preparations of cannabis, cannabinoids and other drugs of abuse for basic and clinical research through its Drug Supply Program currently under the Institute's Division of Basic Neuroscience & Behavioral Research (DBNBR). These materials are unique to this contract and they cannot be duplicated by any other legal means. It is therefore essential that cannabis, marijuana cigarettes, delta-9-THC and other cannabinoids should be made available for research through this contract mechanism.

B. Objectives

The main objectives of this contract are to (1) cultivate, harvest, store, check purity and distribute cannabis; (2) frequently analyze cultivated cannabis and stored material(s) to determine optimum harvesting time, formulation aspects, potency, content uniformity, and stability; (3) manufacture, check strength and stability, and distribute cannabis (marijuana) cigarettes to research investigators; (4) extract cannabis and isolate pure delta-9-THC and other cannabinoids for the NIDA drug supply program; (5) analyze confiscated marijuana and related materials for cannabinoids in order to monitor marijuana potency; analyze herbicide (Paraquat) in confiscated marijuana samples in collaboration with DEA and other federal agencies; and produce quarterly marijuana potency report

for distribution as authorized by NIDA; and (6) conduct research on enhancing the quantity and quality of NIDA grown marijuana and its chemical constituents.

II. Services to Be Performed

A. General Requirements

1. The contract will provide for the production of cannabis, cannabis materials and marijuana cigarettes, their analysis, and shipment to research investigators. Cannabis is used in a large variety of research projects supported by DHHS. This contract serves as the only source of such material in the United States. Sufficient quantities of cannabis are to be grown to meet anticipated needs, followed by careful quantitative analysis and storage prior to shipment to researchers in this country and abroad.

NIDA supplies research investigators with marijuana (cannabis) and its main psychoactive component, delta-9-tetrahydrocannabinol (THC), and other non-psychoactive components such as cannabidiol (CBD) and cannabigerol (CBG) and others. In order to meet present and anticipated need for cannabinoids, the Contractor shall extract THC and other cannabinoids from cannabis from its bulk marijuana stocks and provide purified materials to the NIDA Drug Supply program.

Materials provided through this contract are not available through commercial or other sources, but are essential to investigators involved in drug abuse research. These materials are then unique to this contract and cannot be duplicated by any other legal means. Independently and not as an agent of the Government, the Contractor shall be required to furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government.

The contractor shall grow cannabis and provide for or manufacture and maintain a stock of cannabis preparations such as marijuana cigarettes and various cannabinoids for distribution as required by NIDA, and as necessary to fulfill the requirements set forth below. The contractor shall analyze cannabis samples for cannabinoid contents. All pertinent FDA and DEA requirements (e.g., Good Manufacturing Practices) must be met for the preparations.

The contractor shall serve as NIDA's cannabis drug repository and keep these products in proper storage conditions to maintain their purity, integrity and strength.

2. All work under this contract shall be monitored by the Government Contracting Officer's Technical Representative (COTR) who is defined in Section G of this contract.

B. Specific Requirements

Specifically, the Contractor shall perform the following:

1. Grow, harvest, store, ship and analyze cannabis of different varieties, as required. More specifically, the Contractor shall:

A). Plant, grow, and harvest research grade cannabis (composed predominantly of Mexican and Colombian varieties and occasionally, Indian, Turkish or other varieties) for basic and clinical research. Harvesting shall be carried out by selecting appropriate plant parts and appropriate harvest time as to day and hour based on continuous monitoring of plants by chemical analysis for key cannabinoids. In order to minimize spoilage, the collected material shall be dried in an efficient and expeditious manner and placed in the storage. NOTE: The current inventory of cannabis shall be available for initial use under this contract.

A minimum quantity of approximately 30 Kg of cannabis shall be required during the contract duration. If additional quantity is required, the NIDA will exercise Option 2 with additional funds.

B). Analyze samples in triplicate of harvested plant materials for delta-9 THC and other cannabinoid concentration. Complete analysis of all batches of cannabis shall be performed every year during the contract duration.

C). Quantitatively determine the major cannabinoids in harvested cannabis samples by gas liquid chromatography (GLC) and/or other suitable methods. Minimally this will require the quantification of delta-9-THC, cannabidiol (CBD), cannabichromene (CBC), cannabidiol (CBN), delta-8-THC, and cannabigerol (CBG). Some samples may require analysis for THC acids A and B.

D). Reanalyze samples of crops from previous years to determine viability of samples. Generally this will require one analysis per batch or storage container per year.

E). Perform analysis of marijuana samples submitted by the DEA, other law enforcement agencies, and/or by others as designated by the NIDA COTR. Samples shall come from seizures of marijuana, hashish and hash oil. Results of analysis shall be sent in writing to the submitting source(s) within a month of receipt of the samples to be analyzed. The analyses on these samples generally will consist of same cannabinoids as for the harvested material. In addition, specific samples will be analyzed for herbicides used for marijuana eradication which could contaminate confiscated samples.

An average of between 100 and 150 samples from DEA are to be analyzed each month for both cannabinoids and herbicide (Paraquat), respectively. These analyses should be quantitative and capable of herbicide detection to at least 5 ppm.

F). Develop new methods for growing very low (for placebo) and high THC yielding cannabis plants that may include developing and refining a protocol for in vitro propagation of cannabis plants under controlled condition, and evaluation of the effect of growth regulators on cannabis biomass and THC yield.

2. Provide adequate DEA approved storage facility and store cannabis, and cannabis materials including required cannabinoids and marijuana cigarettes, at optimal temperature. More specifically, the contractor shall:

- Store available marijuana plant materials including previous crops in appropriate containers at 75°F to minimize chemical degradation for low THC containing samples; and high THC containing materials at 30°F to 40°F. The contract shall maintain a minimum stock of 250 Kg of bulk plant materials and have storage capacity of approximately 500 Kg of such materials.
- Storage and record keeping of all materials shall be in accordance with the current DEA requirements. Local DEA agents will determine the exact type of security required. Cannabis belonging to NIDA shall be stored in a secure room(s) reserved for that purpose, and specially equipped to provide necessary security.
- Maintain a database system containing all pertinent analytical data on individual sample analyses.

3. Develop and manufacture standardized marijuana cigarettes, within a range of specified delta-9-THC content, and placebos as authorized by the NIDA COTR for use in pre-clinical and clinical research programs. The contractor shall manufacture 2,000 placebo, and 8,000 of each low, medium, and high delta-9-THC containing marijuana cigarettes once in 5 years.

If additional quantity of marijuana cigarettes is required, the NIDA will exercise Option 3 with additional funding.

Unless otherwise authorized in writing by the NIDA Contracting Officer, the Contractor shall maintain a minimum stock of the following for use in research projects:

- 25,000 Standardized marijuana cigarettes, Placebo (THC content, 0.0%)
- 25,000 Standardized marijuana cigarettes, Low (THC content, 1.0 - 2.5%)
- 25,000 Standardized marijuana cigarettes, Medium (THC content, 2.5 - 3.5%)
- 50,000 Standardized marijuana cigarettes, High (THC content, 3.5 - 5%)

Upon NIDA authorization, the contractor shall distribute these cigarettes for research.

4. Manufacture small batches of marijuana cigarettes (500 to 1,000) containing high concentration of delta-9-THC (greater than 5.0%) as required by the NIDA COTR. This may require hand rolling of the cigarettes.

5. Extract cannabis to manufacture pure (>95%) delta-9-THC and other cannabinoids, such as cannabidiol (CBD), cannabinol (CBN), cannabigerol (CBG), cannabichromene (CBC), THCv, and other cannabinoids as required by the NIDA COTR for the NIDA drug supply inventory.

The contractor shall manufacture the following per year:

- a). delta-9-THC - 500.00 g
- b). CBD - 20.00 g
- c). CBN - 10.00 g

- d). CBG, CBC, and THCV - 1.00 g, each
6. Upon NIDA authorization, supply pure (>95%) cannabinoids to the NIDA drug supply inventory.
7. Provide adequate DEA approved storage facility and store marijuana cigarettes and other cannabinoids at -20°F or below as appropriate.
8. Provide appropriate information and assist the NIDA COTR in preparing/updating documents for Drug Master File (DMF) or related submissions to the US. Food & Drug Administration as needed.
9. Carry out stability studies at three months interval, or as directed by the NIDA COTR, on bulk materials (harvested and stored cannabis materials), and marijuana cigarettes; and perform quality control testing on new and previously manufactured marijuana cigarettes to assure their authenticity, purity and strength.
10. Ship bulk cannabis, marijuana cigarettes, and other cannabinoids upon NIDA authorization for research and/or to the NIDA drug supply repository, or as directed by the NIDA COTR. In some cases, NIDA may authorize appropriate fees to be charged for these supplies. In such cases, the fees shall be charged at a rate specified by the NIDA which may be adjusted as necessary. Only the NIDA COTR shall have the authority to waive the fee. For shipments made under the single patient IND program, and NIDA/NIH supported research, a fee will not be charged. Approximately 100 shipments per year are expected. The Contractor shall:
- a. Maintain a facility, or make the appropriate arrangements, to enable requests to be received within five (5) working days after contract award; and allow shipments to be made within (10) working days after contract award.
 - b. Receive requests and maintain a log of requests for materials and other information. To facilitate a prompt response to requests, the NIDA COTR may pre-authorize any normal recurring requests that the Contractor will then fill once it has received the appropriate assurances under subparagraph c. below. All other requests should be submitted to the NIDA COTR for approval. If there is a reason to question a particular request, the Contractor shall inform the NIDA COTR who will make a final decision on providing the material and quantity requested. Requests for shipment submitted by the NIDA COTR shall take precedence over all other requests.
 - c. Obtain and maintain records of properly completed and signed Order and Assurance Forms, and Release and Indemnity Agreements, from all individuals requesting materials. Completed forms must be received prior to shipping materials and for normal recurring requests, must be renewed annually. A copy of the Release and Indemnity Agreement is included under Section J of the contract. The Order and Assurance Form is to be developed by the Contractor, but at a minimum, the Form should contain information on the following:
 - 1). An indication of the funding source, e.g., NIDA researcher, other NIH Researcher, other Government researcher, Non-Government researcher.
 - 2). An appropriate registration with DEA
 - 3). An indication of appropriate FDA/IND approvals.
 - 4). The type and amount of material(s) being requested.
 - 5). The date by which the item will be required.
 - 6). An assurance that the material(s) being provided will not be resold.
 - 7). An agreement that the material(s) will be used only for research or patient purposes.
 - 8). An agreement that the use of the material(s) will adhere to appropriate Safety Standards for Research.
 - 9). An agreement to comply with all Federal, State and Local Safety requirements for use of the material(s).
 - 10). A brief statement of the intended use
 - d. Upon NIDA COTR approval, ship the requested materials from inventory within 14 calendar days after receipt of a signed Order and Assurance Form, the Release and Indemnity Agreement, and payment (if prepayment is required).
 - e. Appropriately package, label and ship all materials according to regulations concerning transport of DEA Schedule materials. The Contractor shall provide all necessary materials for packaging, labeling and shipping.
 - f. Provide appropriate characterization data to recipients with all distributed materials.
 - g. Collect monies for materials distributed according to the established price to be determined by NIDA. The specified price may be updated periodically. The Contractor shall account for all shipments and receipts,

including \$0 shipments, in accordance with the Cost Recovery Procedures/Monthly Shipment & Sales Summary, (see Section G, Article G.3 and Section J, Attachment 10 of the contract.)

11. Employ NIDA Drug Inventory Supply Control System (DISCS) database for supply and shipment records of cannabis, marijuana cigarettes, cannabinoids and any other preparations of cannabis that are shipped by the contractor . This extensive inventory and shipment tracking system is maintained on an ORACLE Database system with Visual Basic on NIDA's Local Area contractor. In other words, monitor exact quantities on hand, adjust inventories of all batches of cannabis, various cannabinoids, marijuana cigarettes and others, re-purifications and reduction in amount following shipment, produce shipping documents, providing tracking of shipping orders at the contractor site.

12. Maintain a separate account of all preparations shipped and costs recovered, and summarize all monthly shipments and reimbursements received from recipients. See Section J for a copy of the form for reporting the Monthly Summary of Shipment and Sales.

13. Dispose of contaminated and/or unusable materials in accordance with appropriate regulations.

14. Prepare and submit monthly progress reports to the NIDA COTR on all activities in the project including preparation, analysis, and shipping of marijuana cigarettes, and related products.

15. Phase-In Requirements (this task will be performed only if other than the incumbent contractor receives the follow-on award)

a. The Contractor shall receive current inventory of cannabis, marijuana cigarettes, and any cannabinoids available under the current contract in various quantities for immediate storage.

b. NIDA will cover shipping costs for its inventory items and equipment, if any, to the contractor's location.

c. The contractor shall have a secure and DEA approved facility for storage and distribution of inventoried cannabis, marijuana cigarettes and various cannabinoids.

d. The contractor shall have and maintain an indoor facility for the purpose of propagating and sustaining cannabis plants under controlled condition. A facility of approximately 1000 square feet with controls for light intensity, photo cycles, humidity, and carbon dioxide concentration may be needed.

e. The Contractor shall employ a Government database system (Drug Inventory Supply Control System, DISCS) for the purpose of updating and maintaining relevant information on relevant supply and inventory.

f). Arrangements for a site visit to the existing facilities for the new Contractor shall be arranged.

C. Schedule of Work

The services provided by the Contractor in Option Years 2-5 of the contract shall be identical to the services described in Year 1.

D. Option Requirements

Option 1 Upon exercise of this option, the Contractor shall:

Cultivate, grow, harvest, analyze, and store research grade cannabis, as specified in detail under this Statement of Work in one of the following amounts:

1a. 1.5 acres

1b. 6.5 acres

Individual options may be exercised as and when warranted during the duration of the contract. Notification of intent to exercise an option under the Statement of Work will be provided to the Contractor on or before March 15 of the year in which the option is to be exercised.

Option 2. Upon the exercise of this option by the Government, as specified under the Statement of Work the Contractor shall manufacture the following:

2a. 5,000 Standardized marijuana cigarettes, Placebo (THC content, 0.0%)

- 2b. 15,000 Standardized marijuana cigarettes, Low (THC content, 1.0 - 2.5%)
- 2c. 15,000 Standardized marijuana cigarettes, Medium (THC content, 2.5 - 3.5%)
- 2d. 15,000 Standardized marijuana cigarettes, High (THC content, 3.5 - 5%)
- 2e. 1,000 Standardized marijuana cigarettes, Very High (THC content, >5%)

In accordance with the option clause of the contract, any or all items under option 2 may be exercised once or multiple times depending upon the need, but will not exceed 51,000 marijuana cigarettes in total for any single contract year.

Option 3 - Training and Transitional Support

Upon exercise of this option, the Contractor shall provide up to 3 months of transitional support and training and devote up 470 person hours as described below. This option may be exercised only one time, in the event that a follow-on contract is awarded to other than the incumbent contractor.

The Contractor shall provide up to a three month period for the training and transitional support in the following areas:

- a). Review and training on the existing data base system containing all pertinent analytical data on individual sample analyses, drug supply, and inventory balance, as well as a copy of the system which will be delivered to the new Contractor;
- b). As required, appropriate training in marijuana farming, analysis, security, DEA regulations and marijuana cigarette manufacturing, in order to ensure that all requirements can be met;
- c). Arrangements for a site visit to the existing facilities for the new Contractor;
- d). Transfer of any Government property; and, training and developmental costs associated with specific analytical laboratory procedures required for the contract.

To ensure continuity of services, the Government shall exercise this option no later than three months prior to contract expiration date.

NIDA will cover the cost of shipments to the new contractor's location.

Option 4 - Option Years

Year 2 Option

The Government reserves the right to exercise this option to extend the contract for an additional year. If exercised, the contractor shall carry out tasks identical to those stated for the Base Year including the Quantity Options. The Government will evaluate the progress of this contract 9 months after the effective date and decide within 30 days whether to exercise the option.

Year 3 Option

The Government reserves the right to exercise this option to extend the contract for an additional year. If exercised, the contractor shall carry out tasks identical to those stated for the Base Year including the Quantity Options. The Government will evaluate the progress of this contract 21 months after the effective date and decide within 30 days whether to exercise the option.

Year 4 Option

The Government reserves the right to exercise this option to extend the contract for an additional year. If exercised, the contractor shall carry out tasks identical to those stated for the Base Year including the Quantity Options. The Government will evaluate the progress of this contract 33 months after the effective date and decide within 30 days whether to exercise the option.

Year 5 Option

The Government reserves the right to exercise this option to extend the contract for an additional year. If exercised, the contractor shall carry out tasks identical to those stated for the Base Year including the Quantity

Options. The Government will evaluate the progress of this contract 45 months after the effective date and decide within 30 days whether to exercise the option.

ARTICLE C.2. REPORTING REQUIREMENTS

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

a. Technical Progress Reports

1. In addition to the required reports set forth elsewhere in this Schedule, the preparation and submission of regularly recurring Technical Progress Reports will be required in any contract resulting from this solicitation. These reports will require descriptive information about the activities undertaken during the reporting period and will require information about planned activities for future reporting periods. The frequency and specific content of these reports will be determined prior to contract award.

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

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

2. **Summary of Salient Results**

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

b. **Other Reports/Deliverables**

1. **Information Security Reporting Requirements**

The Contractor shall submit the following reports as required by the INFORMATION SECURITY Article in SECTION H of this contract. Note: Each report listed below includes a reference to the appropriate subparagraph of this article.

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. Any revisions to the roster as a result of staffing changes shall be submitted within 15 calendar days of the change. (Reference subparagraph c.(2) of the INFORMATION SECURITY Article in SECTION H of this contract.)

b. Information Security Training Report

The Contractor shall maintain a listing by name and title of each employee (including subcontractors) working under this contract that has completed the NIH required information security training. Any additional security training completed by Contractor/Subcontractor staff shall be included on this listing. The listing of completed training shall be included in the first technical progress report. (See Article C.2.a. Technical Progress Reports.) Any revisions to this listing as a result of staffing changes shall be submitted with next required technical progress report. (Reference subparagraph d. of the INFORMATION SECURITY Article in SECTION H of this contract.)

c. Reporting of New and Departing Employees

The Contractor shall notify the Contracting Officer's Technical Representative (COTR) and Contracting Officer within five business days of staffing changes for positions that require suitability determinations as follows (Reference subparagraph f. of the INFORMATION SECURITY Article in SECTION H of this contract.):

(1) **New Employees:** Provide the name, position title, e-mail address, and phone number of the new employee. Provide the name, position title and suitability level held by the former incumbent. If the employee is filling a new position, provide a description of the position and the Government will determine the appropriate security level.

(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

d. 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/security/Nondisclosure.pdf>. (Reference subparagraph g. of the INFORMATION SECURITY Article in SECTION H of this contract.)

e. Self Assessment & Information Security Plan Reporting

(1) **NIST SP 800-53 Self-Assessment** (Reference subparagraph h. of the INFORMATION SECURITY Article in SECTION H of this contract.)

The contractor shall annually update and resubmit its Self-Assessment required by NIST SP 800-53, Recommended Security Controls for Federal Information Systems to the Contracting Officer's Technical Representative (COTR), with a copy to the Contracting Officer no later than the completion date of the period of performance. (<http://csrc.nist.gov/publications> - under Special Publications).

The Contractor's annual update to its Self-Assessment Questionnaire shall include similar information for any subcontractor that performs under the SOW to (1) develop a Federal information system(s) at the Contractor's/Subcontractor's facility, or (2) host and/or maintain a Federal information system(s) at the Contractor's/Subcontractor's facility.

(2) Information System Security Plan (Reference subparagraph i. of the INFORMATION SECURITY Article in SECTION H of this contract.)

The Contractor's draft ISSP submitted with its proposal shall be finalized in coordination with the COTR no later than 90 calendar days after contract award.

Following approval of its draft ISSP, the Contractor shall update and resubmit its ISSP to the COTR every three years or when a major modification has been made to its internal system. The Contractor shall use the current ISSP template in Appendix A of NIST SP 800-18, Guide to Developing Security Plans for Federal Information Systems. (<http://csrc.nist.gov/publications/nistpubs/800-18-Rev1/sp800-18-Rev1-final.pdf>).

The Contractor shall include similar information for any subcontractor performing under the SOW with the Contractor whenever the submission of an ISSP is required.

2. Section 508 Annual Report

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

ARTICLE C.3. INVENTION REPORTING REQUIREMENT

All reports and documentation required by FAR Clause 52.227-11, Patent Rights-Ownership by the Contractor including, but not limited to, the invention disclosure report, the confirmatory license, and the Government support certification, shall be directed to the Extramural Inventions and Technology Resources Branch, OPERA, NIH, 6705 Rockledge Drive, Room 2207, MSC 7987, Bethesda, Maryland 20892-7987 (Telephone: 301-435-1986). In addition, one copy of an annual utilization report, and a copy of the final invention statement, shall be submitted to the Contracting Officer. The final invention statement (see FAR 27.303(b)(2)(ii)) shall be submitted to the Contracting Officer on the expiration date of the contract.

The first annual utilization report shall be due on or before March 15, 2011. Thereafter, reports shall be due on or before the last Calendar day following the reporting period. The final invention statement (see FAR 27.303(b)(2)(ii)) shall be submitted on the expiration date of the contract. All reports shall be sent to the following address:

Contracting Officer
NIDA R&D Contracts Management Branch
National Institute on Drug Abuse
Neurosciences Office of Acquisition
6101 Executive Blvd., Rm. 260
MSC 8402
Bethesda, Maryland 20892- 8402

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

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

SECTION D - PACKAGING, MARKING AND SHIPPING

a. 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.

b. All items shall be preserved, packaged and marked to meet the requirements for controlled substances per the DEA (Drug Enforcement Agency) and the packaging requirements of the carrier, including that which may be necessary to prevent deterioration and damages due to the hazards of weather, shipping, handling, and storing. The cigarettes shall be packed with approximately 300 per canister. Labeling shall be suitable to meet FDA requirements and shall follow the instructions from the Code of Federal Regulations regarding such substances. Labeling shall be adequate to meet the requirements to support IND (Investigational New Drug). The quantity shall be determined after recipient's request has been received. The labeling shall conform to FDA and CFR requirements, and be adequate to meet the requirements to support an IND.

SECTION E - INSPECTION AND ACCEPTANCE

- a. The Contracting Officer or the duly authorized representative will perform inspection and acceptance of materials and services to be provided.
- b. For the purpose of this SECTION, the Contracting Officer's Technical Representative (COTR) is the authorized representative of the Contracting Officer.
- c. Inspection and acceptance will be performed at:
NIH/NIDA
6001 Executive Blvd.
Bethesda, MD 20892

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

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

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

SECTION F - DELIVERIES OR PERFORMANCE

ARTICLE F.1. PERIOD OF PERFORMANCE

- a. The period of performance of this contract shall be from March 2010 through March 2011.
- b. If the Government exercises its option(s) pursuant to the OPTION PROVISION Article in Section H of this contract, the period of performance will be increased as listed below:

| Option | Option Period |
|---------------------------------|-------------------------|
| Option Year 1 (Contract Year 2) | March 2011 - March 2012 |
| Option Year 2 (Contract Year 3) | March 2012 - March 2013 |
| Option Year 3 (Contract Year 4) | March 2013 - March 2014 |
| Option Year 4 (Contract Year 5) | March 2014 - March 2015 |

ARTICLE F.2. DELIVERIES

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

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

| Item | Description | Quantity | Delivery Schedule |
|------|--|------------------------------|--|
| (1) | Monthly Report | 1 electronic, 2 hard | On or before the 5th day of each month |
| (2) | Quarterly Report on Potency Monitoring | 1 electronic, 2 hard | On or before the 5th day after the end of the quarter |
| (3) | Semi-Annual Report | 1 electronic, 2 hard | On or before the 15th of the month, no monthly report will be required when this report is due |
| (4) | Annual Report | 1 electronic, 1 CD, & 3 hard | On or before the 15th of the month following the end of the contract year if option years are exercised, no monthly or semi-annual report will be required when this report is due |
| (5) | Final Report | 1 electronic, 1 CD, & 3 hard | Upon contract completion, no monthly, semi-annual, or annual report will be required when this report is due. |
| (6) | Summary of Salient Results | 1 electronic, 3 hard | Upon contract completion, with final report. |

| Item | Description | Quantity | Delivery Schedule |
|------|--|----------------------|--|
| (7) | Roster of Employees Requiring Suitability Investigations | 1 hard | Within 14 calendar days of the effective day of the contract, and within 15 calendar days of any change. |
| (8) | Information Security Training Report | 1 electronic, 1 hard | Within 14 calendar days of the effective day of the contract, and within 15 calendar days of any change. |
| (9) | Reporting of New & Departing Employees | 1 hard | Within 14 calendar days of the effective day of the contract, and within 15 calendar days of any change. |
| (10) | Contractor - Employee Non-Disclosure Agreement(s) | 1 hard | Within 14 calendar days of the effective day of the contract, and within 15 calendar days of any change. |
| (11) | NIST SP 800-53 Self-Assessment | 2 hard | Include with annual reports |
| (12) | Information System Security Plan (final) | 1 hard | Within 90 days after contract award |
| (13) | Section 508 Annual Report | 2 hard | Include with annual reports |
| (14) | Invention Report | 1 hard | Annually & final upon contract completion |

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

| Addressee | Deliverable Item No | Quantity |
|---|---------------------------------------|-----------------------------------|
| COTR, 6001 Executive Blvd., Bethesda, MD 20892 | 1, 2, 3, 4, 5, 6, 7, 8, 9,10,11,12,13 | 1 electronic, 1 CD, and/or 2 hard |
| Contracting Officer, 6101 Executive Blvd., Bethesda, MD 20892 | 4, 5, 6, 13,14 | 1 hard |

ARTICLE F.3. LEVEL OF EFFORT

a. During the period of performance of this contract, the Contractor shall provide 9870 direct labor Hours . The labor Hours Exclude vacation, holiday, and sick leave. These labor Hours Include subcontractor labor Hours . It is estimated that the labor Hours are constituted as specified below and will be expended approximately as follows:

Labor HOURS

| Labor Category | Year 1 | Option Year 2 | Option Year 3 | Option Year 4 | Option Year 5 |
|----------------------------|--------|---------------|---------------|---------------|---------------|
| Professional (PhD) | 1880 | 1880 | 1880 | 1880 | 1880 |
| Professional (MA or below) | 1880 | 1880 | 1880 | 1880 | 1880 |
| Professional Support | 2350 | 2350 | 2350 | 2350 | 2350 |

| Labor Category | Year 1 | Option Year 2 | Option Year 3 | Option Year 4 | Option Year 5 |
|------------------------|--------|---------------|---------------|---------------|---------------|
| Administrative Support | 1880 | 1880 | 1880 | 1880 | 1880 |
| Other Support | 1880 | 1880 | 1880 | 1880 | 1880 |

Option QUANTITIES

| | Year 1 | Option Year 2 | Option Year 3 | Option Year 4 | Option Year 5 |
|-----------|--------|---------------|---------------|---------------|---------------|
| Option 1a | 3295 | 3295 | 3295 | 3295 | 3295 |
| Option 1b | 6115 | 6115 | 6115 | 6115 | 6115 |
| Option 2a | 750 | 750 | 750 | 750 | 750 |
| Option 2b | 311 | 311 | 311 | 311 | 311 |
| Option 2c | 311 | 311 | 311 | 311 | 311 |
| Option 2d | 308 | 308 | 308 | 308 | 308 |
| Option 2e | 200 | 200 | 200 | 200 | 200 |
| Option 3 | 470 | 470 | 470 | 470 | 470 |

- b. The Contractor shall have satisfied the requirement herein if not less than 90% nor more than 110% of the total direct labor Hours specified herein are furnished.
- c. In the event fewer Hours than the minimum specified number of direct labor Hours in the total categories are used by the Contractor in accomplishing the prescribed work and the Government has not invoked its rights under FAR Clause 52.249-6, TERMINATION (Cost-Reimbursement) incorporated in this contract, these parties agree that the fee will be adjusted based solely upon the quantity of Hours by which the number of direct labor Hours furnished is less than the number of direct labor Hours specified in this ARTICLE. The resulting adjustment shall be evidenced by a contract modification.

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/comp/far/index.html>

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:

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

SECTION G - CONTRACT ADMINISTRATION DATA

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

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

[To be provided at time of Award.]

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

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

The Contracting Officer hereby delegates the COTR as the Contracting Officer's authorized representative responsible for signing software license agreements issued as a result of this contract.

The Government may unilaterally change its COTR designation.

ARTICLE G.2. KEY PERSONNEL, HHSAR 352.270-5 (January 2006)

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

(End of Clause)

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

| Name | Title |
|--------------------------------------|-------|
| [To be determined at time of Award.] | |

ARTICLE G.3. COST RECOVERY PROCEDURES/MONTHLY SALES SUMMARY

- a. During the course of this contract, the Contracting Officer or his duly designated representative will notify the Contractor to make certain shipments of cannabis products directly to specified U.S. Government Recipients, Contractors, Government Agencies, or other private organizations and the Contractor shall make such shipments as directed.
- b. The Contractor shall bill recipients directly for the cannabis products provided. The charges for these products shall be based upon the current National Institute on Drug Abuse price list for the items listed in an Attachment in SECTION J, of this contract. Under no circumstances shall the Contractor bill prices other than those listed in

the referenced price list. Prices listed are subject to change. Revised price lists will be issued by the Government when appropriate without the concurrence of the Contractor.

- c. The Contractor shall keep an accurate account of all payments received from recipients separate from other fiscal aspects of the contract. The Contractor shall record as credits on monthly invoices to the Government, all payments received from the Government Grantees, Contractors, Government Agencies, or other private organizations. The income from recipients must be credited to the Government in the billing period actually received. Thus, the Contractor shall bill the Government directly for payment of contract costs and shall subtract as a credit all payments received from recipients. The actual collections from sales shall be offset against the gross billing, leaving a net amount due on the invoice.

The National Institute on Drug Abuse Contracting Officer's Technical Representative (COTR) may direct from time to time that shipments be made entirely at Government expense.

- d. The Contractor shall account for the contract related income separately in accordance with its own double entry accounting system. The Contractor shall submit to the Government a Monthly Summary Sheet of Sales, which is listed as an Attachment in SECTION J of this contract. The Contractor shall submit a copy of this Attachment each month with the Monthly Progress Report.

The administration of the contract related income shall be subject to the terms of this contract, including specifically and without limitation, FAR Clause 52.215-2, Audit and Records--Negotiation, of the General Clauses (including applicable Alternates), and the applicable cost principles of the Federal Acquisition Regulation.

- e. The Contractor shall use the following procedures for collection of delinquent accounts:

Step 1 - Accounts 30 days past due. A copy of the invoice shall be sent to the recipient with a notation that the account is overdue and request payment.

Step 2 - Accounts 60 days past due. The Contractor shall turn the account over to a collection agency.

- f. When the completion (final) invoice is submitted on this contract, a listing of all outstanding recipient invoices shall be provided along with details as to what disposition is expected on each.
- g. The contractor shall establish a mechanism for receipt of advance payments and/or COD to facilitate shipments and cost recovery features of the contract.

ARTICLE G.4. INVOICE SUBMISSION

- a. Invoice/Financing Request Instructions for NIH Cost-Reimbursement Type Contracts NIH(RC)-1 are attached and made part of this contract. The Contractor shall follow the attached instructions and submission procedures specified below to meet the requirements of a "proper invoice" pursuant to FAR Subpart 32.9, Prompt Payment.

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

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

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

- b. Two copies of the invoice shall be submitted to the following **approving official** with appropriate backup documentation as indicated in Exhibit A to the NIH(RC)-1:

Contracting Officer

NIDA R&D Contracts Management Branch
 Neurosciences Office of Acquisitions
 6101 Executive Blvd., Rm 260
 MSC 8402
 BETHESDA, MD 20892- 8402

2. In addition to the requirements specified in FAR 32.905 for a proper invoice, the Contractor shall include the following information on the face page of all payment requests:
- a. Name of the Office of Acquisitions. The Office of Acquisitions for this contract is the Neurosciences Office of Acquisitions, NIDA R&D Contracts Management Branch .
 - b. Central Point of Distribution. For the purpose of this contract, the Central Point of Distribution is NIDAinvoicesNIDACMB@NIDA.NIH.GOV . (NOTE: Contractors are not to submit invoices to this e-mail address.)
 - 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 Number. Each payment request must be identified by a unique invoice number, which can only be used one time regardless of the number of contracts or orders held by an organization.
- b. Inquiries regarding payment of invoices shall be directed to the designated billing office, (301) 496-6452.
- c. The Contractor shall include the following certification on every invoice for reimbursable costs incurred with Fiscal Year funds subject to the SALARY RATE LIMITATION LEGISLATION PROVISIONS Article in SECTION H 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 SALARY RATE LIMITATION LEGISLATION PROVISIONS Article in SECTION H of the above referenced contract."

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
 6100 Building, Room 6B05
 6100 EXECUTIVE BLVD MSC-7540

BETHESDA MD 20892-7540

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

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

http://www.hhs.gov/oamp/policies/contractors_guide_for_control_of_gov_property.pdf.

ARTICLE G.7. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

a. Contractor Performance Evaluations

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

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

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

b. Electronic Access to Contractor Performance Evaluations

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

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

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

SECTION H - SPECIAL CONTRACT REQUIREMENTS

ARTICLE H.1. HUMAN SUBJECTS

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

ARTICLE H.2. SALARY RATE LIMITATION LEGISLATION PROVISIONS

- a. The Contractor shall not use NIH Fiscal Year funds to pay the direct salary of an individual through this contract at a rate in excess of Executive Level I. Direct salary is exclusive of fringe benefits, overhead and general and administrative expenses (also referred to as "indirect costs" 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. The annual salary rate limitation also applies to individuals proposed under subcontracts. It does not apply to fees paid to consultants. If this is a multiple year contract, it may be subject to unilateral modifications by the Government if an individual's salary rate used to establish contract funding exceeds any salary rate limitation subsequently established in future HHS appropriation acts.
- b. Payment of direct salaries is limited to the Executive Level I rate which was in effect on the date(s) the expense was incurred. 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 / cursor to bottom of page and select year / Executive Schedule / Rates of Pay for the Executive Schedule. Rates are effective January 1 of each calendar year unless otherwise noted.)*

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

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

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

ARTICLE H.4. NEEDLE EXCHANGE

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

ARTICLE H.5. PRESS RELEASES

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

amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

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

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

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

ARTICLE H.7. LIMITATION ON USE OF FUNDS FOR PROMOTION OF LEGALIZATION OF CONTROLLED SUBSTANCES

The Contractor shall not use contract funds to support activities that promote the legalization of any drug or other substance included in schedule I of the schedules of controlled substances established under section 202 of the Controlled Substances Act (21 U.S.C. 812), except for normal and recognized executive-congressional communications. This limitation shall not apply when the Government determines that there is significant medical evidence of a therapeutic advantage to the use of such drug or other substance or that federally sponsored clinical trials are being conducted to determine therapeutic advantage.

ARTICLE H.8. DISSEMINATION OF FALSE OR DELIBERATELY MISLEADING SCIENTIFIC INFORMATION

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

ARTICLE H.9. RESTRICTION ON EMPLOYMENT OF UNAUTHORIZED ALIEN WORKERS

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

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

ARTICLE H.10. PRIVACY ACT, HHSAR 352.270-11 (January 2006)

This contract requires the Contractor to perform one or more of the following: (a) Design; (b) develop; or (c) operate a Federal agency system of records to accomplish an agency function in accordance with the Privacy Act of 1974 (Act) (5 U.S.C. 552a(m)(1)) and applicable agency regulations. The term "system of records" means a group of any records under the control of any agency from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual.

Violations of the Act by the Contractor and/or its employees may result in the imposition of criminal penalties (5 U.S.C. 552a(i)). The Contractor shall ensure that each of its employees knows the prescribed rules of conduct and that each employee is aware that he/she is subject to criminal penalties for violation of the Act to the same extent as HHS employees. These provisions also apply to all subcontracts awarded under this contract which require the design, development or operation of the designated system(s) of records (5 U.S.C. 552a(m)(1)).

The contract work statement: (a) Identifies the system(s) of records and the design, development, or operation work to be performed by the Contractor; and (b) specifies the disposition to be made of such records upon completion of contract performance.

(End of clause)

45 CFR Part 5b contains additional information which includes the rules of conduct and other Privacy Act requirements and can be found at: http://www.access.gpo.gov/nara/cfr/waisidx_06/45cfr5b_06.html.

The Privacy Act System of Records applicable to this project is Number 09-25-0200. This document is incorporated into this contract as an Attachment in SECTION J of this contract. This document is also available at: <http://oma.od.nih.gov/ms/privacy/pa-files/read02systems.htm>.

ARTICLE H.11. OPTION PROVISION

Unless the Government exercises its option pursuant to the Option Clause set forth in ARTICLE 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 52.217-7, Option for Increased Quantity-Separately Priced Line Item and FAR Clause 52.217-9, Option to Extend the Term of the Contract set forth in ARTICLE I.3. of this contract, the Government may, by unilateral contract modification, require the Contractor to perform additional options set forth in the Statement of Work and also defined in Sections C and F of the contract. If the Government exercises this option, notice must be given at least 60 days prior to the expiration date of this contract, and the estimated cost of the contract will be increased as set forth in the ESTIMATED COST Article in SECTION B of this contract.

ARTICLE H.12. SUBCONTRACTING PROVISIONS

a. Small Business Subcontracting Plan

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

b. Subcontracting Reports

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

1. Individual Subcontract Reports (ISR)

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

April 30th
 October 30th
 Expiration Date of Contract

2. Summary Subcontract Report (SSR)

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

October 30th

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

nidaesrsreports@nida.nih.gov

ARTICLE H.13. INFORMATION SECURITY

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

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

a. Information Type

Administrative, Management and Support Information

Mission Based Information

b. Security Categories and Levels

Confidentiality Level: Low Moderate High

Integrity Level: Low Moderate High

Availability Level: Low Moderate High

Overall Level: Low Moderate High

c. Position Sensitivity Designations

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

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

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

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

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

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

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

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

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

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

d. Information Security Training

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

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

e. Rules of Behavior

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

f. Personnel Security Responsibilities

Contractor Notification of New and Departing Employees Requiring Background Investigations

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

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

1. Contractor Agreement

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

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

2. Contractor-Employee Non-Disclosure Agreements

Each Contractor/Subcontractor employee who may have access to non-public Department information under this contract shall complete the Commitment to Protect Non-Public Information - Contractor Agreement. A copy of each signed and witnessed Non-Disclosure agreement shall be submitted to the Contracting Officer's Technical Representative (COTR) prior to performing any work under the contract.

h. NIST SP 800-53 Self-Assessment

The contractor shall annually update and re-submit its Self-Assessment required by NIST SP 800-53, *Recommended Security Controls for Federal Information Systems*. (<http://csrc.nist.gov/publications> - under Special Publications).

Subcontracts: The Contractor's annual update to its Self-Assessment Questionnaire shall include similar information for any subcontractor that performs under the SOW to (1) develop a Federal information system(s) at the Contractor's/Subcontractor's facility, or (2) host and/or maintain a Federal information system(s) at the Contractor's/Subcontractor's facility.

The annual update shall be submitted to the Contracting Officer's Technical Representative (COTR), with a copy to the Contracting Officer, on the contract anniversary date.

i. Information System Security Plan

The Contractor's draft ISSP submitted with its proposal shall be finalized in coordination with the Contracting Officer's Technical Representative (COTR) no later than 90 calendar days after contract award.

Following approval of its draft ISSP, the Contractor shall update and resubmit its ISSP to the COTR every three years or when a major modification has been made to its internal system. The Contractor shall use the current ISSP template in Appendix A of NIST SP 800-18, *Guide to Developing Security Plans for Federal Information Systems*. (<http://csrc.nist.gov/publications/nistpubs/800-18-Rev1/sp800-18-Rev1-final.pdf>). The details contained in the Contractor's ISSP shall be commensurate with the size and complexity of the requirements of the SOW based on the System Categorization determined above in subparagraph (b) Security Categories and Levels of this Article.

Subcontracts: The Contractor shall include similar information for any subcontractor performing under the SOW with the Contractor whenever the submission of an ISSP is required.

j. Common Security Configurations

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

ARTICLE H.14. STORAGE FACILITY REQUIREMENTS AND CERTIFICATION

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

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

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

ARTICLE H.15. ELECTRONIC AND INFORMATION TECHNOLOGY ACCESSIBILITY (January 2008)

Pursuant to Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998, all electronic and information technology (EIT) products and services developed, acquired, maintained, and/or used under this contract/order must comply with the "Electronic and Information Technology Accessibility Provisions" set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the "Access Board") in 36 CFR part 1194. Information about Section 508 provisions is available at <http://www.section508.gov/>. The complete text of Section 508 Final provisions can be accessed at <http://www.access-board.gov/sec508/provisions.htm>.

The Section 508 standards applicable to this contract/order are identified in the Statement of Work. The contractor must provide a written Section 508 conformance certification due at the end of each order/contract exceeding \$100,000 when the order/contract duration is one year or less. If it is determined by the Government that EIT products and services provided by the Contractor do not conform to the described accessibility in the Product Assessment Template, remediation of the products and/or services to the level of conformance specified in the vendor's Product Assessment Template will be the responsibility of the Contractor at its own expense.

In the event of a modification(s) to the contract/order, which adds new EIT products and services or revised the type of, or specifications for, products and services the Contractor is to provide, including EIT deliverables such as electronic documents and reports, the Contracting Officer may require that the contractor submit a completed HHS Section 508 Product Assessment Template to assist the Government in determining that the EIT products and services support Section 508 accessibility requirements. Instructions for documenting accessibility via the HHS Section 508 Product Assessment Template may be found at <http://508.hhs.gov>.

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

Prior to the Contracting Officer exercising an option for a subsequent performance period/additional quantity or adding increment funding for a subsequent performance period under this contract, as applicable, the Contractor must provide a Section 508 Annual Report to the Contracting Officer and Contracting Officer's Technical Representative (COTR). Unless otherwise directed by the Contracting Officer in writing, the Contractor shall provide the cited report in accordance with the following schedule. Instructions for completing the report are available at: <http://508.hhs.gov/> under the heading Vendor Information and Documents. The Contractor's failure to submit a timely and properly completed report may jeopardize the Contracting Officer's exercising an option or adding incremental funding, as applicable.

Schedule for Contractor Submission of Section 508 Annual Report:

Annually or on the contract anniversary date

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

ARTICLE H.16. CONFIDENTIALITY OF INFORMATION/USE OF DATA

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

All data collected, generated, manipulated, or otherwise processed under this contract are subject to the Confidentiality of Information Clause (HHSAR 352.224.70) of this contract.

Information and data collected, generated, manipulated or otherwise processed under this contract shall be treated as confidential. This requires the contractor to provide the Contracting Officer advance written notice of at least 45 days of the contractor's intent to release findings associated with this data. The Government fully intends to allow the contractor to publish such findings, subject to customary privacy and proprietary/confidentiality concerns.

It is noted that if the Government allows use of the data for any purpose other than direct contract performance, it may be released to any interested party. To facilitate such release, the Government reserves the option to require the contractor to provide any or all data to other offerors, to develop a "Public Use Tape," with accompanying instructions guiding users on the interpretation and use of contract data materials, or to develop summary datasets or tabulations. Costs to perform such data preparation tasks will be considered allowable under the contract.

All requests which the contractor receives from third parties for access to the data must be referred promptly to the COTR.

ARTICLE H.17. INSTITUTIONAL RESPONSIBILITY REGARDING CONFLICTING INTERESTS OF INVESTIGATORS

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

<http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr;sid=9f130b6d2d48bb73803ca91ce943be3a;rgn=div5;view=text;node=45%3A1.0.1.1.53;idno=45;cc=ecfr>

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

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

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

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

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

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

ARTICLE H.18. PUBLICATION AND PUBLICITY

In addition to the requirements set forth in HHSAR Clause **352.270-6, Publications and Publicity** incorporated by reference in SECTION I of this contract, the Contractor shall acknowledge the support of the National Institutes of Health whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

"This project has been funded in whole or in part with Federal funds from the National Institute in Drug Abuse, National Institutes of Health, Department of Health and Human Services, under Contract No. [To be determined at time of award.]"

ARTICLE H.19. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

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

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

ARTICLE H.20. YEAR 2000 COMPLIANCE

The contractor warrants that each commercial and/or noncommercial item of hardware, software, and firmware used, delivered or developed under this contract shall be able to accurately process date/time 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, and be able to properly exchange date/time data with other information technology, used in combination with the information technology being acquired.

The remedies available to the Government under this warranty include repair, database reconfiguration or replacement of any item whose noncompliance is discovered and made known to the contractor within ninety (90) days after contract expiration. The contractor shall be responsible for absorbing any cost of such remedies. Nothing in this warranty shall be construed to limit any rights or remedies the Government otherwise may have under this contract with respect to defects other than Year 2000 performance.

ARTICLE H.21. OBTAINING AND DISSEMINATING BIOMEDICAL RESEARCH RESOURCES

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

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

ARTICLE H.22. CONSTITUTION DAY

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

PART II - CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

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

The complete listing of these clauses may be accessed at:

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

ARTICLE I.1. General Clauses for a Cost-Reimbursement Contract with Educational Institutions

ARTICLE I.1. General Clauses for a Cost-Reimbursement Contract with Non-Profit Organizations Other Than Educational Institutions

ARTICLE I.1. General Clauses for a Cost-Reimbursement Research and Development Contract

ARTICLE I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES

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

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

- a. FAR Clauses **52.215-15, Pension Adjustments And Asset Reversions** (October 2004); **52.215-18, Reversion Or Adjustment Of Plans For Post Retirement Benefits (PRB) Other Than Pensions** (July 2005); and, 52.215-19, **Notification Of Ownership Changes** (October 1997), are deleted in their entirety.
- b. **Alternate IV** (October 1997) of FAR Clause **52.215-21, Requirements For Cost Or Pricing Data Or Information Other Than Cost Or Pricing Data--Modifications** (October 1997) is added.
- c. **Alternate II** (October 2001) of FAR Clause **52.219-9, Small Business Subcontracting Plan** (April 2008) is added.
- d. FAR Clauses **52.249-6, Termination (Cost-Reimbursement)** (May 2004) and **52.249-14, Excusable Delays** (April 1984), are deleted in their entirety and FAR Clause **52.249-5, Termination for Convenience of the Government (Educational and Other Nonprofit Institutions)** (September 1996), is substituted therefore.

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 **52.204-9, Personal Identity Verification of Contractor Personnel** (September 2007).

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

3. FAR Clause **52.217-7, Option for Increased Quantity - Separately Priced Line Item** (March 1989).

"...The Contracting Officer may exercise the option by written notice to the Contractor within 60 days of the end of each applicable contract year"

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

"(a) The Government may extend the term of this contract by written notice to the Contractor within 30 days of contract expiration ; provided that the Government gives the Contractor a preliminary written notice of its intent to extend at least 60 days before the contract expires. The preliminary notice does not commit the Government to an extension."

"(c) The total duration of this contract, including the exercise of any options under this clause, shall not exceed 5 years."

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

"(c) Waiver of evaluation preference.....
 Offeror elects to waive the evaluation preference."

6. FAR Clause **52.219-25, Small Disadvantaged Business Participation Program--Disadvantaged Status and Reporting** (April 2008).

7. FAR Clause **52.224-1, Privacy Act Notification** (April 1984).

8. FAR Clause **52.224-2, Privacy Act** (April 1984).

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

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

11. FAR Clause **52.230-2, Cost Accounting Standards** (October 2008).

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

13. FAR Clause **52.230-5, Cost Accounting Standards - Educational Institution** (October 2008).

14. FAR Clause **52.230-6, Administration of Cost Accounting Standards** (March 2008).

15. FAR Clause **52.232-18, Availability of Funds** (April 1984).

16. FAR Clause **52.239-1, Privacy or Security Safeguards** (August 1996).

17. FAR Clause **52.242-3, Penalties for Unallowable Costs** (May 2001).

18. FAR Clause **52.243-2, Changes--Cost Reimbursement** (August 1987), **Alternate V** (April 1984).

19. FAR Clause **52.251-1, Government Supply Sources** (April 1984).

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

1. HHSAR Clause **352.223-70, Safety and Health** (January 2006).

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

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

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

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

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

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

This contract incorporates the following clauses in full text.

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

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

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

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

Small business concern means a concern, including its affiliates, that is independently owned and operated, not dominant in the field of operation in which it is bidding on Government contracts, and qualified as a small business under the criteria in 13 CFR part 121 and the size standard in paragraph (c) of this clause. Such a concern is "not dominant in its field of operation" when it does not exercise a controlling or major influence on a national basis in a kind of business activity in which a number of business concerns are primarily engaged. In determining whether dominance exists, consideration shall be given to all appropriate factors, including volume of business, number of employees, financial resources, competitive status or position, ownership or control of materials, processes, patents, license agreements, facilities, sales territory, and nature of business activity.

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

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

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

(3) For long-term contracts--

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

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

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

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

(e) Except as provided in paragraph (g) of this clause, the Contractor shall make the rerepresentation required by paragraph (b) of this clause by validating or updating all its representations in the Online Representations and Certifications Application and its data in the Central Contractor Registration, as necessary, to ensure that

they reflect the Contractor's current status. The Contractor shall notify the contracting office in writing within the timeframes specified in paragraph (b) of this clause that the data have been validated or updated, and provide the date of the validation or update.

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

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

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

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

(End of clause)

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

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

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

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

Notice to Employees

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(g) The Contractor shall include the substance of this clause in every subcontract or purchase order that exceeds the simplified acquisition threshold, entered into in connection with this contract, unless exempted by the Department of Labor Deputy Assistant Secretary for Labor-Management Programs on account of special circumstances in the national interest under authority of 29 CFR 470.3(c). For indefinite quantity subcontracts, the Contractor shall include the substance of this clause if the value of orders in any calendar year of the subcontract is expected to exceed the simplified acquisition threshold. Pursuant to 29 CFR part 470, Subpart B--Compliance Evaluations, Complaint Investigations and Enforcement Procedures, the Secretary of Labor may direct the Contractor to take such action in the enforcement of these regulations,

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

(End of Clause)

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

The following documents are incorporated into this RFP:

SOLICITATION ATTACHMENTS

| Attachment No. | Title | Location |
|----------------|--|---|
| Attachment 1: | Packaging and Delivery of Proposal (R & D) | Attached to this RFP |
| Attachment 2: | Proposal Intent Response Sheet | http://www.nida.nih.gov/funding/intentall.html |

TECHNICAL PROPOSAL ATTACHMENTS

| Attachment No. | Title | Location |
|----------------|---------------------------------|---|
| Attachment 3: | Technical Proposal Cost Summary | http://www.niaid.nih.gov/contract/forms.htm |
| Attachment 4: | Summary of Related Activities | http://www.niaid.nih.gov/contract/forms.htm |

BUSINESS PROPOSAL ATTACHMENTS

| Attachment No. | Title | Location |
|----------------|--|--|
| Attachment 5: | Proposal Summary and Data Record, NIH-2043 | http://www.niaid.nih.gov/contract/forms.htm |
| Attachment 6: | Small Business Subcontracting Plan | http://www.hhs.gov/osdbu/SubcontractPlan-FY08.doc |
| Attachment 7: | Breakdown of Proposed Estimated Costs (plus fee) w/Excel Spreadsheet | http://oamp.od.nih.gov/contracts/BUSCOST.HTM http://oamp.od.nih.gov/Division/DFAS/spshexcl.xls |
| Attachment 8: | Offeror's Points of Contact | http://www.niaid.nih.gov/contract/forms.htm |
| Attachment 9: | Disclosure of Lobbying Activities, OMB Form SF-LLL | http://rcb.cancer.gov/rcb-internet/forms/sflllin.pdf |

INFORMATIONAL ATTACHMENTS

| Attachment No. | Title | Location |
|----------------|--|---|
| Attachment 10: | Monthly Summary Sheet of Sales | Attached to this RFP. |
| Attachment 11: | Invoice/Financing Request Instructions-CR-NIH(RC)-1 | http://rcb.cancer.gov/rcb-internet/forms/rc1.pdf |
| Attachment 12: | NIDA Supplemental Billing Instructions, Exhibit A to NIH(RC)-1 | http://rcb.cancer.gov/rcb-internet/forms/RC-1-NIDA.pdf |
| Attachment 13: | Privacy Act System of Records | http://oma.od.nih.gov/ms/privacy/pa-files/read02systems.htm |
| Attachment 14: | Safety and Health, HHSAR Clause 352.223-70 | http://rcb.cancer.gov/rcb-internet/forms/safety&health-1-06.pdf |
| Attachment 15: | Procurement of Certain Equipment, NIH(RC)-7 | http://www.niaid.nih.gov/contract/forms/NIH-RC-7.pdf |

| Attachment No. | Title | Location |
|-----------------------|---|---|
| Attachment 16: | Commitment to Protect Non-Public Information Contractor Agreement | http://irm.cit.nih.gov/security/Nondisclosure.pdf |
| Attachment 17: | Roster of Employees Requiring Suitability Investigations | http://ais.nci.nih.gov/forms/Suitability-roster.xls |
| Attachment 18: | Employee Separation Checklist | http://rcb.cancer.gov/rcb-internet/forms/Emp-sep-checklist.pdf |
| Attachment 19: | Release and Indemnity Agreement | Attached to this RFP |

PART IV - REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST :

1. Go to the **Online Representations and Certifications Application (ORCA)** at: <https://orca.bpn.gov/> and complete the Representations and Certifications; and

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

which can be accessed electronically from the INTERNET at the following address:

<http://rcb.cancer.gov/rcb-internet/wkf/sectionk.pdf>

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

SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

1. GENERAL INFORMATION

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

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

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

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

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

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

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

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

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

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

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

(i) The solicitation number;

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

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

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

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

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

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

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

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

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

(3) It is the only proposal received.

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

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

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

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

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

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

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

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

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

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

(e) Restriction on disclosure and use of data.

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

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

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

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

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

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

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

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

(f) Contract award.

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

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

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

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

necessary. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals.

(5) The Government reserves the right to make an award on any item for a quantity less than the quantity offered, at the unit cost or prices offered, unless the offeror specifies otherwise in the proposal.

(6) The Government reserves the right to make multiple awards if, after considering the additional administrative costs, it is in the Government's best interest to do so.

(7) Exchanges with offerors after receipt of a proposal do not constitute a rejection or counteroffer by the Government.

(8) The Government may determine that a proposal is unacceptable if the prices proposed are materially unbalanced between line items or subline items. Unbalanced pricing exists when, despite an acceptable total evaluated price, the price of one or more contract line items is significantly overstated or understated as indicated by the application of cost or price analysis techniques. A proposal may be rejected if the Contracting Officer determines that the lack of balance poses an unacceptable risk to the Government.

(9) If a cost realism analysis is performed, cost realism may be considered by the source selection authority in evaluating performance or schedule risk.

(10) A written award or acceptance of proposal mailed or otherwise furnished to the successful offeror within the time specified in the proposal shall result in a binding contract without further action by either party.

(11) If a post-award debriefing is given to requesting offerors, the Government shall disclose the following information, if applicable:

(i) The agency's evaluation of the significant weak or deficient factors in the debriefed offeror's offer.

(ii) The overall evaluated cost or price and technical rating of the successful and debriefed offeror and past performance information on the debriefed offeror.

(iii) The overall ranking of all offerors, when any ranking was developed by the agency during source selection;

(iv) A summary of the rationale for award.

(v) For acquisitions of commercial items, the make and model of the item to be delivered by the successful offeror.

(vi) Reasonable responses to relevant questions posed by the debriefed offeror as to whether source-selection procedures set forth in the solicitation, applicable regulations, and other applicable authorities were followed by the agency.

(End of Provision)

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 541712.

2. The small business size standard is 500 employees.

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

It is anticipated that one will be made from this solicitation and that the award will be made on/about March 2010.

It is anticipated that the award from this solicitation will be a multiple-year Cost-Reimbursement type Level of Effort contract with a Term of 1year.

d. LEVEL OF EFFORT

The Government's requirement for the work set forth in the Statement of Work of this solicitation is 9870 direct labor hours for the base year. Estimated Direct labor hours for option years and option quantities are set forth below. It is estimated that the labor hours are constituted as specified below and will be expended approximately as follows:

Labor HOURS

| Labor Category | Year 1 | Option Year 2 | Option Year 3 | Option Year 4 | Option Year 5 |
|----------------------------|---------------|----------------------|----------------------|----------------------|----------------------|
| Professional (PhD) | 1880 | 1880 | 1880 | 1880 | 1880 |
| Professional (MA or below) | 1880 | 1880 | 1880 | 1880 | 1880 |
| Professional Support | 2350 | 2350 | 2350 | 2350 | 2350 |
| Administrative Support | 1880 | 1880 | 1880 | 1880 | 1880 |
| Other Support | 1880 | 1880 | 1880 | 1880 | 1880 |

Option QUANTITIES

| Option | Year 1 | Option Year 2 | Option Year 3 | Option Year 4 | Option Year 5 |
|---------------|---------------|----------------------|----------------------|----------------------|----------------------|
| Option 1a | 3295 | 3295 | 3295 | 3295 | 3295 |
| Option 1b | 6115 | 6115 | 6115 | 6115 | 6115 |
| Option 2a | 750 | 750 | 750 | 750 | 750 |
| Option 2b | 311 | 311 | 311 | 311 | 311 |
| Option 2c | 311 | 311 | 311 | 311 | 311 |
| Option 2d | 308 | 308 | 308 | 308 | 308 |
| Option 2e | 200 | 200 | 200 | 200 | 200 |
| Option 3 | 470 | 470 | 470 | 470 | 470 |

e. COMMITMENT OF PUBLIC FUNDS

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

f. COMMUNICATIONS PRIOR TO CONTRACT AWARD

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

g. RELEASE OF INFORMATION

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

h. 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
NIDA R&D Contracts Management Branch
National Institute on Drug Abuse
Neurosciences Office of Acquisition
6101 EXECUTIVE BLVD, RM 260 MSC 8402
BETHESDA MD 20892- 8402

(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)

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

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

(End of provision)

2. INSTRUCTIONS TO OFFERORS

a. GENERAL INSTRUCTIONS

INTRODUCTION

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

1. Contract Type and General Clauses

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

2. Authorized Official and Submission of Proposal

The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this RFP. Your proposal shall be submitted in the number of copies, to the addressees, and marked as indicated in the Attachment entitled, PACKAGING AND DELIVERY OF PROPOSAL, Part III, Section J hereof. Proposals will be typewritten, paginated, reproduced on letter size paper and will be legible in all required copies. To expedite the proposal evaluation, all documents required for responding to the RFP should be placed in the following order:

I. COVER PAGE

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

II. TECHNICAL PROPOSAL

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

III. BUSINESS PROPOSAL

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

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

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

4. Separation of Technical and Business Proposals

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

5. Alternate Proposals

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

6. Evaluation of Proposals

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

7. Potential Award Without Discussions

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

8. Use of the Metric System of Measurement

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

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

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

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

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

9. Privacy Act - Treatment of Proposal Information

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

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

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

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

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

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

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

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

10. Selection of Offerors

- a. The acceptability of the scientific and technical portion of each research contract proposal will be evaluated by a technical review committee. The committee will evaluate each proposal in strict conformity with the evaluation criteria of the RFP, utilizing point scores and written critiques. The committee may suggest that the Contracting Officer request clarifying information from an offeror.
- b. The business portion of each contract proposal will be subjected to a cost and price analysis, management analysis, etc.
- c. If award will be made without conducting discussions, offerors may be given the opportunity to clarify certain aspects of their proposal (e.g., the relevance of an offeror's past performance information and adverse past performance information to which the offeror has not previously had an opportunity to respond) or to resolve minor or clerical errors.
- d. If the Government intends to conduct discussions prior to awarding a contract -

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

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

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

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

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

11. Institutional Responsibility Regarding Conflicting Interests of Investigators

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

12. ROTC Access and Federal Military Recruiting on Campus

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

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

13. Past Performance Information

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

A list of the last 3 contracts completed during the past Three years and THE LAST 3 CONTRACTS AWARDED currently being performed that are similar in nature to the solicitation workscope. Contracts listed may include those entered into by the Federal Government, agencies of state and local governments and commercial concerns. Offerors may also submit past performance information regarding predecessor companies, key personnel who have relevant experience or subcontractors that will perform major or critical aspects of the requirement when such information is relevant to the instant acquisition. For the purposes of this solicitation, a "major subcontract" is defined as a subcontract whose value is greater than \$100,000.

Include the following information for each contract or subcontract listed:

1. Name of Contracting Organization
2. Contract Number (for subcontracts, provide the prime contract number and the subcontract number)
3. Contract Type
4. Total Contract Value
5. Description of Requirement

6. Contracting Officer's Name and Telephone Number
7. Program Manager's Name and Telephone Number
8. North American Industry Classification System (NAICS) Code

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

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

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

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

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

Accordingly, any vendor submitting a proposal/quotations/bid in response to this solicitation must demonstrate compliance with the established EIT accessibility provisions. Information about Section 508 provisions is available at <http://www.section508.gov/>. The complete text of Section 508 Final Provisions can be accessed at <http://www.access-board.gov/sec508/provisions.htm>.

The Section 508 standards applicable to this solicitation are identified in the Statement of Work/ Specification/Performance Work Statement. In order to facilitate the Government's evaluation to determine whether EIT products and services proposed meet applicable Section 508 accessibility standards, offerors must prepare an HHS Section 508 Product Assessment Template, in accordance with its completion instructions, and provide a binding statement of conformance. The purpose of the template is to assist HHS acquisition and program officials in determining that EIT products and services proposed support applicable Section 508 accessibility standards. The template allows vendors or developers to self-evaluate their products or services and document in detail how they do or do not conform to a specific Section 508 standard. Instructions for preparing the HHS Section 508 Product Assessment Template may be found at <http://508.hhs.gov>.

Respondents to this solicitation must also provide any additional detailed information necessary for determining applicable Section 508 standards conformance, as well as for documenting EIT products and/or services that are incidental to the project, which would constitute an exception to Section 508 requirements. If a vendor claims its products and/or services, including EIT deliverables such as electronic documents and reports, meet applicable Section 508 standards in its completed HHS Section 508 Product Assessment Template, and it is later determined by the Government - i.e., after award of a contract/order, that products and/or services delivered do not conform to the described accessibility in the Product Assessment Template, remediation of the products and/or services to the level of conformance specified in the vendor's Product Assessment Template will be the responsibility of the Contractor at its expenses.

(End of provision)

15. 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. *Data Universal Numbering System (DUNS) Number, FAR Provision 52.204-6 (April 2008).*
- b. *Facilities Capital Cost of Money, FAR Clause 52.215-16, (October 1997).*
- c. *Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8, (October 1997).*

b. TECHNICAL PROPOSAL INSTRUCTIONS

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

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

1. Technical Discussions

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

a. Statement of Work**1. Objectives**

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

2. Approach

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

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

3. Methods

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

4. Schedule

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

b. Personnel

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

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

1. Single Principal Investigator/Project Director

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

2. Other Investigators

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

3. Additional Personnel

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

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

4. Resumes

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

2. Other Considerations

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

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

3. Technical Evaluation

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

4. Obtaining and Disseminating Biomedical Research Resources

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

the fundamental concepts and Guidelines that provide specific information to patent and license professionals and sponsored research administrators for implementation.

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

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

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

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

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

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

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

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

a. Information Type

Administrative, Management and Support Information:

Mission Based Information:

b. Security Categories and Levels

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

c. Position Sensitivity Designations

Prior to award, the Government will determine the position sensitivity designation for each Contractor (including subcontractor) employee that the successful offeror proposes for

work under the contract. For proposal preparation purposes, the following designations apply:

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

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

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

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

<http://ais.nci.nih.gov/forms/Suitability-roster.xls>

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

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

d. Information Security Training

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

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

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

e. Offeror's Official Responsible for Information Security

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

f. NIST SP 800 53 Self Assessment

The offeror must include in the "Information Security" part of its Technical Proposal, a completed Self-Assessment required by NIST Draft SP 800-53, Recommended Security Controls for Federal Information Systems. (<http://csrc.nist.gov/publications> - under Special Publications).

Subcontracts: The offeror must include similar information for any proposed subcontractor that will perform under the SOW to (1) develop a Federal information system(s) at the offeror's/subcontractor's facility, or (2) host and/or maintain a Federal information system(s) at the offeror's/subcontractor's facility.

g. Draft Information System Security Plan

The offeror must include a draft Information System Security Plan (ISSP) using the current template in Appendix A of NIST SP 800 18, Guide to Developing Security Plans for Federal Information Systems (<http://csrc.nist.gov/publications/nistpubs/800-18-Rev1/sp800-18-Rev1-final.pdf>). The details contained in the offeror's draft ISSP must be commensurate with the size and complexity of the requirements of the SOW based on the System Categorization determined above in subparagraph (b) Security Categories and Levels.

Subcontracts: The offeror must include similar information for any proposed subcontractor that will perform under the SOW with the offeror whenever the submission of an ISSP is required.

Note to Offeror: The resultant contract will require the draft ISSP to be finalized in coordination with the Contracting Officer's Technical Representative (COTR) no later than 90 calendar days after contract award. Also, a contractor is required to update and resubmit its ISSP to NIH every three years following award or when a major modification has been made to its internal system.

h. Common Security Configurations

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

i. References

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

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

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

4. NIST Special Publication 800-16, Information Technology Security Training Requirements; and Appendix A-D

5. NIST SP 800-18, Guide for Developing Security Plans for Information Technology Systems
6. NIST SP 800-26, Revision 1, Computer Security
7. NIST SP 800-53, Revision 1, Recommended Security Controls for Federal Information Systems
8. NIST SP 800-60, Guide for Mapping Types of Information and Information Systems to Security Categories, Volume I; and Volume II, Appendices to Guide For Mapping Types of Information and Information Systems To Security Categories, Appendix C, and Appendix D
9. NIST SP 800-64, Security Considerations in the Information System Development Life Cycle
10. FIPS PUB 199, Standards for Security Categorization of Federal Information and Information Systems
11. FIPS PUB 200, Minimum Security Requirements for Federal Information and Information Systems

c. **BUSINESS PROPOSAL INSTRUCTIONS**

1. **Basic Cost/Price Information**

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

2. **Proposal Cover Sheet**

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

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

This cover sheet information is for use by offerors to submit information to the Government when cost or pricing data are not required but information to help establish price reasonableness

or cost realism is necessary. Such information is not considered cost or pricing data, and shall not be certified in accordance with FAR 15.406-2.

3. Information Other than Cost or Pricing Data

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

Any information submitted must support the price proposed. Include sufficient detail or cross references to clearly establish the relationship of the information provided to the price proposed. Support any information provided by explanations or supporting rationale as needed to permit the Contracting Officer and authorized representative to evaluate the documentation.

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

1. Direct Labor

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

2. Materials

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

3. 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 \$550,000, 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.

4. Raw Materials

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

5. Purchased Parts

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

6. 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.

7. Indirect Costs

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

8. **Special Equipment**

If direct charge, list any equipment in accordance with Item (9) Other Administrative Data, subparagraph a.(2) Government Property of this Section L.2.c of this solicitation.

9. **Travel**

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

10. **Other Costs**

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

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

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

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

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

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

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

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

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

(2) The offeror grants the Contracting Officer or an authorized representative the right to examine, at any time before award, books, records, documents, or other directly pertinent records to verify any request for an exception under this provision, and the reasonableness

of price. For items priced using catalog or market prices, or law or regulation, access does not extend to cost or profit information or other data relevant solely to the offeror's determination of the prices to be offered in the catalog or marketplace.

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

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

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

(End of provision)

5. Salary Rate Limitation in Fiscal Year 2010

Offerors are advised that pursuant to P.L. **, no NIH Fiscal Year 2010 (October 1, 2009 - September 30, 2010) funds may be used to pay the direct annual salary of an individual through any contract awarded as a result of this solicitation at a rate in excess of the Executive Schedule, Level I* (direct salary is exclusive of Overhead, Fringe Benefits and General and Administrative expenses, also referred to as "indirect cost" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the Contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patient care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the Contractor.

This does not preclude the offeror from absorbing that portion of an employee's annual salary (plus the dollar amount for fringe benefits and associated indirect costs) that exceeds a rate of the Executive Schedule, Level I*. The salary rate limitation set by P.L. ** applies only to Fiscal Year 2010 funds, however, salary rate ceilings for subsequent years may be included in future DHHS appropriation acts. Multi-year contracts awarded pursuant to this solicitation may be subject to unilateral modifications by the Government if an individual's annual salary exceeds any salary rate ceiling established in future appropriations acts. The Executive Schedule, Level I* annual salary rate limitation also applies to individuals proposed under subcontracts, however it does not apply to consultants. P.L. ** states in pertinent part:

"None of the funds appropriated in this Act for the National Institutes of Health, the Agency for Healthcare Research and Quality, and the Substance Abuse, and Mental Health Services Administration shall be used to pay the salary of an individual through a grant or other extramural mechanism at a rate in excess of Executive Level I*."

LINK TO EXECUTIVE SCHEDULE SALARIES: <http://www.opm.gov/oca/09tables/pdf/ex.pdf>

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

**Pending Passage of Legislation.

6. Small Business Subcontracting Plan

If the proposed contract exceeds a total estimated cost of \$550,000 for the entire period of performance, the offeror shall be required to submit an acceptable subcontracting plan in accordance with the terms of the clause entitled "Small Business Subcontracting Plan," FAR Clause No. 52.219-9, incorporated herein by reference in the Solicitation, See SECTION J - LIST OF ATTACHMENTS, BUSINESS PROPOSAL ATTACHMENTS of this RFP for an example of such a plan.

- a. THIS PROVISION DOES NOT APPLY TO SMALL BUSINESS CONCERNS.
- b. The term "subcontract" means any agreement (other than one involving an employer-employee relationship) entered into by a Federal Government prime Contractor or subcontractor calling for supplies or services required for the performance of the original contract or subcontract. This includes, but is not limited to, agreements/purchase orders for supplies and services such as equipment purchase, copying services, and travel services.
- c. The offeror understands that:
 1. No contract will be awarded unless and until an acceptable plan is negotiated with the Contracting Officer which plan will be incorporated into the contract, as a material part thereof.
 2. An acceptable plan must, in the determination of the Contracting Officer, provide the maximum practicable opportunity for Small Businesses, Small Disadvantaged Businesses, Women-Owned Small businesses, HUBZone Small Businesses, Veteran-Owned Small Businesses, and Service Disabled Veteran-Owned Small Businesses to participate in the performance of the contract.
 3. If a subcontracting plan acceptable to the Contracting Officer is not negotiated within the time limits prescribed by the contracting activity and such failure arises out of causes within the control and with the fault or negligence of the offeror, the offeror shall be ineligible for an award. The Contracting Officer shall notify the Contractor in writing of the reasons for determining a subcontracting plan unacceptable early enough in the negotiation process to allow the Contractor to modify the plan within the time limits prescribed.
 4. Prior compliance of the offeror with other such subcontracting plans under previous contracts will be considered by the Contracting Officer in determining the responsibility of the offeror for award of the contract.
 5. It is the offeror's responsibility to develop a satisfactory subcontracting plan with respect to Small Business Concerns, Small Disadvantaged Business Concerns, Women-Owned Small Business Concerns, HUBZone Small Business Concerns, Veteran-Owned Small Business Concerns, and Service Disabled Veteran-Owned Small Business Concerns that each such aspect of the offeror's plan will be judged independent of the other.
 6. The offeror will submit, as required by the Contracting Officer, subcontracting reports in accordance with the instructions thereon, and as further directed by the Contracting Officer. Subcontractors will also submit these reports to the Government's Contracting Officer or as otherwise directed, with a copy to the prime Contractor's designated small and disadvantaged business liaison.
- d. Each plan must contain the following:
 1. Goals, expressed in terms of percentages of total planned subcontracting dollars, for the use of Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Business Concerns as subcontractors.
 2. A statement of total dollars planned to be subcontracted. A statement of total dollars to be subcontracted to each of the following type of small business concerns: Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.
 3. A description of the principal types of supplies and services to be subcontracted with an identification of which supplies and services are expected to be subcontracted to Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned and/or Service Disabled Veteran-Owned Small Business Concerns.
 4. A description of the method used to develop the subcontracting goals.

5. A description of the method used to identify potential sources for solicitation purposes.
6. A statement as to whether or not indirect costs were included in establishing subcontracting goals. If they were, a description of the method used to determine the proportionate share of indirect costs to be incurred with Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.
7. The name of the individual employed by the offeror who will administer the offeror's subcontracting program and a description of his/her duties.
8. A description of the efforts the offeror will make to assure that Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses have an equitable chance to compete for subcontracts.
9. Assurances that the offeror will include in all subcontracts the contract clause "Utilization of Small Business Concerns." Assure that all subcontractors, other than small businesses, in excess of \$550,000 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:

40% 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.

7. HUBZone Small Business Concerns

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

8. Extent of Small Disadvantaged Business Participation

In accordance with FAR Subpart 15.304(c)(4), the extent of participation of Small Disadvantaged Business (SDB) concerns in performance of the contract in the authorized NAICS Industry Subsectors shall be evaluated in unrestricted competitive acquisitions expected to exceed \$550,000 (\$1,000,000 for construction) subject to certain limitations (see FAR 19.1202-1 and 19.1202-2(b)). The dollar amounts cited above include any option years/option quantities that may be included in this solicitation. The definition of a "small disadvantaged business" is cited in FAR 19.001.

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

The Department of Commerce determines, on an annual basis, by Subsectors, as contained in the North American Industry Classification System (NAICS) 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.arnet.gov/References/sdbadjustments.htm>.

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

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

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

EXAMPLE

Targets for SDB Participation - NAICS Industry Subsector 223

| | SDB Percentage of Total Contract Value | SDB Dollars |
|--|---|--------------------|
| 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.

9. Other Administrative Data

a. Property

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

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

2. Government Property

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

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

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

3. Government-Furnished Property

No Government Furnished Property is offered for this acquisition

4. The management and control of any Government property shall be in accordance with the HHS Publication entitled, Contractors Guide for Control of Government Property, which can be found at: http://www.hhs.gov/oamp/policies/contractors_guide_for_control_of_gov_property.pdf

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

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

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

(End of Provision)

c. Financial Capacity

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

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

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

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

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

(End of Provision)

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

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

Fac Cap Cost of Money (Has Not) **has not** specifically identified or proposed facilities capital cost of money in its proposal and elects not to claim it as an allowable cost under the contract.

10. Qualifications of the Offeror

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

a. General Experience

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

b. Organizational Experience Related to the RFP

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

c. Performance History

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

d. Pertinent Contracts

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

e. Pertinent Grants

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

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

11. Subcontractors

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

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

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>

12. Proposer's Annual Financial Report

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

13. Travel Costs/Travel Policy

a. Travel Costs - Commercial

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

b. Travel Policy

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

SECTION M - EVALUATION FACTORS FOR AWARD

1. GENERAL

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

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

2. MANDATORY QUALIFICATION CRITERIA

Listed below are mandatory qualification criteria. THE OFFEROR SHALL INCLUDE ALL INFORMATION WHICH DOCUMENTS AND/OR SUPPORTS THE QUALIFICATION CRITERIA IN ONE CLEARLY MARKED SECTION OF ITS PROPOSAL.

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

A. In order to handle substances under the Controlled Substances Act of 1970, the successful offeror must possess a current DEA registration for schedule II to V substances and demonstrate the capability to obtain DEA registration for Schedule I controlled substances including marijuana and its active and non-active constituents. In addition the successful offeror must also possess DEA registration for research, manufacture, and distribution of Schedule I through V controlled substances before the award of this contract.

B. The offeror must possess, and maintain (1) a secure and video monitored outdoor facility for growing and processing cannabis, and (2) an indoor growing facility for the purpose of growing, propagating, and sustaining cannabis plants under controlled conditions. A facility of approximately 1000 square feet is required, having controls for light intensity, photo cycles, temperature, humidity, and carbon dioxide concentration.

C. The offeror must demonstrate the availability of a DEA approved and secure storage (vault) facility to maintain an inventory of approximately 200 to 400 Kg of marijuana stock and its active and inactive constituents under controlled conditions.

D. The offeror and/or offeror's subcontractor responsible for the production/manufacture of marijuana cigarettes must be registered with the FDA as a pharmaceutical manufacturer for both sterile products and for drug dosage forms.

3. EVALUATION OF OPTIONS

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

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

4. TECHNICAL EVALUATION CRITERIA

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

1. Understanding the Project 25 points

We will evaluate your technical proposal on how well it shows your comprehensive understanding of the project's goals, objectives, and tasks as called for in the Statement of Work (SOW). This includes an evaluation of how thorough is your background discussion of the work contemplated under this project, including applicable laws, data availability, time and other critical issues related to successful project completion. We will evaluate your understanding of the tasks to be performed, their interrelation and complexity. We will evaluate your discussion of anticipated problems and constraints likely to be encountered in performing the work, and your plans, solutions, and approaches to resolve them. We will also evaluate your experience in understanding of maintenance of shipment and supply records of controlled substances.

2. Technical Approach 30 points

We will evaluate your technical approach for soundness, practicality, and feasibility to accomplish the tasks and requirements of the Statement of Work. More specifically, we will evaluate for efficacy (a) your discussion of the steps proposed to accomplish each task; (b) your detailed explanations of the methodologies to be employed for the production and analysis of cannabis at the levels of purity and potency requested and in the quantities needed; (c) your proposed work plan for production, analysis, quality control, storage, distribution, complex bookkeeping records on shipment/inventory systems; (d) the ability to manufacture marijuana cigarettes at the levels of purity and potency requested and in quantities needed; (e) familiarity with FDA drug approval process and previous experience in dosage form development of controlled substances, especially of marijuana/THC; (f) ability to meet critical issues and performance/delivery schedules under the required tasks which will lead to successful completion of the project; and (g) your discussion of anticipated major difficulties and problem areas, and recommended approaches for their solution.

3. Management Plan 10 points

We will evaluate your management plan on its ability to effectively conduct, manage, and coordinate the resources to ensure successful operation of the technical plan and carry out the proposed project. We will evaluate how appropriate, detailed, effective, and feasible is your management plan showing a task loading chart depicting how the project will be administered, time commitments met and distributed among the project functions.

More specifically, we will also evaluate your management plan on how clear, appropriate, and effective are its following components.

- A person-loading chart that includes staff and any consultants. This chart shall list by task the specific persons involved and their estimated level of effort by either days or hours;
- Organizational charts delineating lines of authority and reporting responsibilities for staff and any consultants; coordinating with NIDA and proposed subcontractor(s); and plans for quality control and organizational backup;
- A milestone chart addressing tasks and scheduling of deliverables.

4. Personnel 25 points

We will evaluate resumes of key personnel, consultants, and any subcontractors for appropriateness of credentials, training, qualifications, experience, and competence to carry out the project. Basic credentials for proposed personnel will be evaluated for experience in production of plant materials, expertise in natural products chemistry, analytical chemistry (use of and interpretation of data from HPLC, GC, GC-MS, LC-MS, and LC-MS/MS), and organic synthesis. In addition, the experience in manufacturing, dosage form development, stability studies; and familiarity with FDA approval processes, GMPs, GLPs, preparation of DMF; and estimation of prices for materials supplied such as marijuana cigarettes, bulk marijuana, seeds of various pedigrees, and collection of sales proceeds from requestors as specified are also needed. At least two Ph.D. level scientists with extensive and relevant experience should be presented and their credentials evaluated. We will evaluate letters of commitment from consultants and subcontractors on the degree to which they ensure availability of needed expertise.

5. Facilities 10 points

We will evaluate your proposed physical environment, equipment, and facilities for availability (laboratory space, equipment, and instruments, and storage facility as stated under the SOW), time committed to the project, appropriateness, suitability, and efficiency.

5. PAST PERFORMANCE FACTOR

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

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

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

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

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

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

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

6. EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION

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

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

Offers will be evaluated on the following sub-factors:

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

PACKAGING AND DELIVERY OF THE PROPOSAL

Shipment and marking shall be as indicated below:

External Package Marking:

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

RFP No. N01DA-10-7773
Attention: Amy Sheib, Contract Specialist

TO BE OPENED BY AUTHORIZED GOVERNMENT PERSONNEL ONLY

Number of Copies and Address:

TECHNICAL PROPOSAL: ORIGINAL AND 10 COPIES
BUSINESS PROPOSAL: ORIGINAL AND 5 COPIES

THE ORIGINALS MUST BE SO MARKED AND READILY ACCESSIBLE
FOR DATE STAMPING PURPOSES.

TO: If using U.S. Postal Service:

Contracting Officer
NIDA R&D Contracts Management Branch
Neuroscience Office of Acquisitions
National Institute on Drug Abuse, NIH
6101 Executive Boulevard
Room 260, MSC 8402
Bethesda, Maryland 20892-8402

If hand delivered or delivery service:

Contracting Officer
NIDA R&D Contracts Management Branch
Neuroscience Office of Acquisitions
National Institute on Drug Abuse, NIH
6101 Executive Boulevard, Room 260
Rockville, Maryland 20852

NOTICE: The U.S. Postal Service's "Express Mail" does not deliver to the Rockville, Maryland address. Anything sent to the Rockville address via this service will be held at a local post office for pick-up. **The Government is not responsible for picking up any mail at a local post office.**

NOTE: If a proposal is not received at the place, date, and time specified herein, it will be considered a "late proposal" and handled in accordance with HHSAR 352.215-70 LATE PROPOSALS AND REVISIONS (NOV 1986).

MONTHLY SUMMARY OF SHIPMENT & SALES

CONTRACTOR:
CONTRACT NUMBER:
MONTHLY SUMMARY OF SALES DATED:
MONTH OF INVOICE:

PAGE ___ OF ___ PAGES

| Recipient & Organization | Items/ Qty. | Unit Cost | Shipping Date | Shipping Cost | Total Billed | Total Collected | Balance Due | Days Late |
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RELEASE AND INDEMNITY AGREEMENT

The undersigned, _____, of _____ for and in consideration of the sale/transfer to it of _____, as well as other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, does hereby for and on behalf of its successors and assigns, release and forever discharge all departments, agencies, branches, and subdivisions of the United States Government, including but not limited to, the Department of Health and Human Services, the National Institutes of Health and the National Institute on Drug Abuse, as well as (Contractor organization) and its successors and assigns (except for cases of (Contractor) negligence), of and from any and all debts, demands, actions, causes of action, damages, liabilities, obligations, and all claims of any nature or character whatsoever, both at law and in equity, which the undersigned may now or hereafter have or claim against the United States Government or (Contractor) as a result of the sale/transfer to it of _____, including specifically, but not limited to, all claims based on breach of warranties, express or implied, strict liability, or any other act or omission of the United States Government, its employees, or agents.

The undersigned acknowledges that the (Contractor) is transferring _____ TO IT, AS IS, AND WITHOUT WARRANTIES, EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO, WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. The undersigned further acknowledges that the nature of the _____ is not fully understood and that its use may involve dangers or risks not known or fully appreciated. The undersigned further acknowledges the possibility of such dangers and risks, voluntarily, accepts and assumes them.

The undersigned does hereby, for and on behalf of its successors and assigns, agree to defend, indemnify, and hold harmless, the United States Government and its employees and agents, as well as (Contractor) and its successors and assigns (except for cases of (Contractor's) negligence), to the extent permitted by Federal, State and local law, from any claims, damages, demands, suits, actions, judgments, liabilities, costs and expenses (including court costs and attorney's fees), and all claims of any nature or character whatsoever, both at law and in equity, including specifically, but not limited to all claims based upon breach of warranties, express or implied, strict liability, by third persons caused, directly or indirectly, by the sale/transfer of _____ to the undersigned by (Contractor) or arising from, scientific experiments or other authorized or unauthorized use of the _____ by the undersigned, its successors and assignees.

The undersigned has read the foregoing Release and Indemnity Agreement, understands its consequences and executes this Agreement freely and voluntarily.

IN WITNESS WHEREOF, the undersigned sets its hand and seal the ___ day of _____, 200__.

WITNESS: _____ SIGNATURE: _____

TYPED NAME: _____.

And

TITLE: _____

STATE OF: _____ ATTEST: _____

COUNTY OF: _____