

AWARD / CONTRACT		1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 350)	RATING	PAGE OF PAGES 1 45			
2. CONTRACT (Proc Inst. Ident.) NO. HHSN271201000014C		3. EFFECTIVE DATE March 16, 2010	4. REQUISITION / PURCHASE REQUEST PROJECT NO. Req# RFP N01DA-10-7773				
5. ISSUED BY National Institute on Drug Abuse, NIH NIDA R&D Contracts Management Branch Neurosciences Office of Acquisitions 6101 Executive Blvd., Room 260, MSC 8402 Bethesda, MD 20892-8402		6. ADMINISTERED BY (if other than Item 5) CODE					
7. NAME AND ADDRESS OF CONTRACTOR (No. street, city, county, State and ZIP Code) UNIVERSITY OF MISSISSIPPI National Center for Natural Products 137 Coy Waller Complex University, MS 38677 DUNS: 067713560 VIN: 1109422		8. DELIVERY <input type="checkbox"/> FOB ORIGIN <input type="checkbox"/> OTHER (See below)		9. DISCOUNT FOR PROMPT PAYMENT N/A			
11. SHIP TO/MARK FOR See Section F		12. PAYMENT WILL BE MADE BY See Section G		10. SUBMIT INVOICES (4 copies unless otherwise specified) to THE ADDRESS SHOWN IN: ITFM See Section G ARTICLE G.4			
13. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION: <input type="checkbox"/> 10 U.S.C. 2304(c) () <input type="checkbox"/> 41 U.S.C. 253(c) ()		14. ACCOUNTING AND APPROPRIATION DATA DOC: 300N01DA107773 EIN: 1646001159A1 CAN: 08469186 OCC: 25.55 \$500,000 (CR)					
15A. ITEM NO.	15B. SUPPLIES/SERVICES	15C. QUANTITY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT		
1.	"Production, Analysis and Distribution of Cannabis, Marijuana Cigarettes and Related Materials" CONTRACT TYPE: Cost Reimbursement-Term CONTRACT AMOUNT: \$1,169,418 OBLIGATED AMOUNT: \$500,000 PERIOD OF PERFORMANCE: March 16, 2010-March 15, 2011						
15G. TOTAL AMOUNT OF CONTRACT					\$ 1,169,418		
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17. <input checked="" type="checkbox"/> CONTRACTOR'S NEGOTIATED AGREEMENT (Contractor is required to sign this document and return 3 copies to issuing office.)			18. <input type="checkbox"/> AWARD (Contractor is not required to sign this document.) Your offer on Solicitation Number: _____ including the additions or changes made by you which additions or changes are set forth in full above, is hereby accepted as the items listed above and on any continuation sheets. This award consummates the contract which consists of the following documents: (a) the Government's solicitation and your offer, and (b) this award/contract. No further contractual document necessary.				
19A. NAME AND TITLE OF SIGNER (Type or print) Alice M. Clark, Vice Chancellor/ORSP			20A. NAME OF CONTRACTING OFFICER Kenneth E. Goodling, Contracting Officer, NIDA R&D CMB				
19B. NAME OF CONTRACTOR BY <u>Alice M. Clark</u> (Signature of person authorized to sign)		19C. DATE SIGNED 3/16/2010	20B. UNITED STATES OF AMERICA BY <u>Kenneth E. Goodling</u> (Signature of Contracting Officer)		20C. DATE SIGNED 3/16/2010		

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PART I - THE SCHEDULE

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 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

- a. The estimated cost of this contract is \$
- b. Total funds currently available for payment and allotted to this contract are \$500,000. For further provisions on funding see the LIMITATION OF FUNDS clause referenced in Part II, ARTICLE I.2. Authorized Substitutions of Clauses.
- c. It is estimated that the amount currently allotted will cover performance of the contract through March 15, 2011.
- d. The Contracting Officer may allot additional funds to the contract without the concurrence of the Contractor. In addition, any option may be funded incrementally without the concurrence of the contractor.

Growing	Contract Year 1	Option Year 2	Option Year 3	Option Year 4	Option Year 5
Option 1a (1.5 acres)	option year				
Option 1b (6.5 acres)					
Manufacturing					
Option 2a (placebo)					
Option 2b (low THC)					
Option 2c (medium THC)					
Option 2d (high THC)					
Other					
Option 3 (transition)					
Option 4 (option years)					

ARTICLE B.3. PROVISIONS APPLICABLE TO DIRECT COSTS

a. Items Unallowable Unless Otherwise Provided

Notwithstanding the clause, ALLOWABLE COST AND PAYMENT, incorporated in this contract, unless authorized in writing by the Contracting Officer, the costs of the following items or activities shall be unallowable as direct costs:

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. (General purpose equipment is defined as any items of personal property which are usable for purposes other than research, such as office equipment and furnishings, pocket calculators, etc.);
4. Travel to attend general scientific meetings;
5. Foreign travel - See subparagraph b. below;
6. Any fee or other payment for consultation in excess of \$250/day/consultant;
7. Subcontracts requiring approval under FAR 52.244-2;
8. Patient care costs;
9. Accountable Government property (defined as both real and personal property with an acquisition cost of \$1,000 or more and a life expectancy of more than two years) and "sensitive items" (defined and listed in the Contractor's Guide for Control of Government Property), regardless of acquisition value.
10. Food Costs (light refreshments or meals).

b. Travel Costs

1. Domestic Travel

- a. Total expenditures for domestic travel (transportation, lodging, subsistence, and incidental expenses) incurred in direct performance of this contract shall not exceed itemized costs exclusive of subcontracting, without the prior written approval of the Contracting Officer. Additionally, this approved amount is increased by itemized costs/option for each option year exercised.

b. The Contractor shall invoice and be reimbursed for all travel costs in accordance with OMB Circular A-21 - "Cost Principles for Educational Institutions."

2. Foreign Travel

Requests for foreign travel must be submitted at least six weeks in advance and shall contain the following: (a) meeting(s) and place(s) to be visited, with costs and dates; (b) name(s) and title(s) of Contractor personnel to travel and their functions in the contract project; (c) contract purposes to be served by the travel; (d) how travel of Contractor personnel will benefit and contribute to accomplishing the contract project, or will otherwise justify the expenditure of NIH contract funds; (e) how such advantages justify the costs for travel and absence from the project of more than one person if such are suggested; and (f) what additional functions may be performed by the travelers to accomplish other purposes of the contract and thus further benefit the project.

ARTICLE B.4. ADVANCE UNDERSTANDINGS

Other provisions of this contract notwithstanding, approval of the following items within the limits set forth is hereby granted without further authorization from the Contracting Officer.

a. **Predetermined Indirect Costs**

The final amount reimbursable for indirect costs associated with the Statement of Work shall be at the following predetermined rate as set forth in the University of Mississippi rate agreements with Division of Cost Allocation, DHHS dated August 9, 2007 for the period from contract award through contract expiration. the following rate shall be applicable for the full duration of this contract for the work negotiated under Article C.1 of this contract.

Rate	Period Covered	Base
Indirect	Full Contract Period	Modified total costs, consisting of all salaries and wages, fringe benefits, materials, supplies, services, travel and subgrants and subcontracts up to the first \$25,000 of each subgrant or subcontract (regardless of the period covered by the subgrant or subcontract).

b. **Subcontract**

A cost reimbursement type subcontract with Research Triangle Institute, P.O. Box 12194, Research Triangle Park, N.C. for manufacturing for an amount not to exceed \$ [itemized costs] for the period March 16, 2010 - March 15, 2011. Additionally this approved amount is increased by \$ [itemized costs/option] (Contract year 2/Option Year), [itemized costs/option] (Contract year 3/Option Year), [itemized costs/option] (Contract year 4/Option Year), [itemized costs/option year] (Contract year 5/Option Year) for each option year exercised.

c. **Confidential Treatment of Sensitive Information**

The Contractor shall guarantee strict confidentiality of the information/data that it is provided by the Government during the performance of the contract. The Government has determined that the information/data that the Contractor will be provided during the performance of the contract is of a sensitive nature.

Disclosure of the information/data, in whole or in part, by the Contractor can only be made after the Contractor receives prior written approval from the Contracting Officer. Whenever the Contractor is uncertain with regard to the proper handling of information/data under the contract, the Contractor shall obtain a written determination from the Contracting Officer.

d. Contract Number Designation

On all correspondence submitted under this contract, the Contractor agrees to clearly identify the two contract numbers that appear on the face page of the contract as follows:

Contract No. HHSN271201000014C

NIDA Control No. N01DA-10-7773

e. DEA Registration

For the duration of this contract, the Contractor agrees to maintain, at no direct cost to this contract, the required DEA registrations for working with substances under the Controlled Substances Act of 1970. In addition, the Contractor and/or subcontractor shall maintain its FDA registration, as a pharmaceutical manufacturing facility at no direct cost to this contract.

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. STATEMENT OF WORK

a. 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 U.S., 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 U.S. 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 and stored cannabis to determine optimum harvesting time, formulation aspects, potency, content uniformity, and stability; (3) manufacture, check strength and stability, and distribute cannabis (marijuana) cigarettes; (4) extract cannabis and isolate pure delta-9-THC and other cannabinoids for the NIDA drug supply program; (5) analyze DEA confiscated marijuana and related materials for cannabinoid contents 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 upon NIDA authorization.

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), cannabigerol (CBG) and others. In order to meet present and anticipated need for cannabinoids, the Contractor shall extract THC and other cannabinoids 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:

Grow, harvest, store, ship and analyze cannabis of different varieties, as required. The contractor shall provide for analytical method improvement for cannabis analysis. 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 6 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 sampling of each harvest of plant material before shipment in triplicate and submit to NIDA the results of these analyses.

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 and/ or electronically to the submitting source(s) within a month of receipt of the samples. 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. Quarterly reports shall be provided in writing and/or electronically to DEA and other requesting agencies or parties upon NIDA COTR authorization.

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.

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. 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%)

All stock items shall be maintained on a first-in, first-out (FIFO) inventory system, unless otherwise designated by the COTR. If at any time during the course of this contract a request is received which would cause the stock to fall below the minimum specified above, the NIDA COTR shall be apprised. In accordance with the following stated order, requests by the NIDA COTR, NIDA researchers and NIH researchers shall take precedence over all other requests. If required by NIDA through the exercise of Option 2, the Contractor shall manufacture standardized marijuana cigarettes.

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 sufficient quantity of bulk cannabis plants to produce 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.

The contractor shall produce the following per year:

a). delta-9-THC - 200.00 g

b). CBD - 4.00 g

c). CBN - 2.00 g

d). CBG, CBC, and THCv - 0.200 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°C or below as appropriate.

8. Provide appropriate information and assist the NIDA COTR in writing and preparing documents for Drug Master File (DMF) on marijuana and marijuana cigarettes for submission 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. Stability testing should be performed at three (3) months intervals or as recommended by the NIDA COTR. The quarterly

testing is required to be performed on all existing batches and newly manufactured batches of marijuana cigarettes.

10. Ship bulk marijuana, marijuana cigarettes, placebo marijuana cigarettes and other cannabinoids upon NIDA authorization for research and/or to the NIDA drug supply repository. 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 DLA

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, repurifications 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

Sq Footage

 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%)

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 to Labor
Hours 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.

1. Monthly Progress Report

This report shall include a description of the activities during the reporting period, and the activities planned for the ensuing reporting period. The first reporting period consists of the first full month of performance plus any fractional part of the initial month. Thereafter, the reporting period shall consist of each calendar month.

The first report shall be due May 5, 2010. Thereafter, reports shall be due on or before the 5th Calendar day following each reporting period.

2. Quarterly Report on Potency Monitoring

A quarterly marijuana potency monitoring report on the analysis of DFA confiscated samples shall be submitted to the NIDA COTR. This report may be supplied to any requestor, if authorized by the COTR.

3. Semi-Annual Progress Report

a. This report shall include a description of the activities during the reporting period and the activities planned for the ensuing reporting period. The initial report will be submitted for the first full six months of the contract performance including any fractional part of the initial month. Thereafter, the reporting period shall consist of six full calendar months.

b. Monthly reports will not be submitted the month the semi-annual report is due.

c. The first report shall be due October 15, 2010. Thereafter, reports shall be due on or before the 15th Calendar day following each reporting period.

4. Annual Progress Report

The report will be required when any subsequent option year is exercised. This report shall include a summation of the results of the entire contract work for the period covered. An annual report will not be required for the period when the Final Report is due. Monthly and Semi-Annual Reports shall not be submitted when an Annual Report is due.

The first report shall cover the period March 16, 2010 through March 15, 2011 of this contract and shall be due on March 15, 2011. Thereafter, reports shall be due on or before the 15th Calendar day following the reporting period.

5. Final Report

This report shall consist of the work performed and results obtained for the entire contract period of performance as stated in SECTION F of this contract. This report shall be in sufficient detail to describe comprehensively the results achieved. The Final Report shall be submitted on or before the last day of the contract performance period. An Annual report shall not be required for the period when the Final Report is due.

6. Summary of Salient Results

The Contractor shall submit, with the Final Report, a summary (not to exceed 200 words) of salient results achieved during the performance of the contract.

a. 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 Division of Extramural Inventions and Technology Resources (DEITR), OPERA, OER, NIH, 6705 Rockledge Drive, Suite 310, MSC 7980, Bethesda, Maryland 20892-7980 (Telephone: 301-435-1986). In addition, one copy of an annual utilization report, and a copy of the final invention statement, shall be submitted to the Contracting Officer. The final invention statement (see FAR 27.303(b)(2)(ii)) shall be submitted to the Contracting Officer on the expiration date of the contract.

The annual utilization report shall be submitted in accordance with the DELIVERIES Article in SECTION F of this contract. 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 Administration) and the packing 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 a 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, Contracting Officer Technical Representative is the authorized representative of the Contracting Officer.
- c. Inspection and acceptance will be performed at:
National Institute on Drug Abuse, NIH
Division of Basic Neuroscience & Behavioral Research
6001 Executive Blvd. Rm. 4261, MSC 9555
Bethesda, MD 20892-9555

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 52.246-9, Inspection of Research and Development (Short Form) (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 16, 2010 through March 15, 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 16, 2011 - March 15, 2012
Option Year 2, Contract Year 3	March 16, 2012 - March 15, 2013
Option Year 3, Contract Year 4	March 16, 2013 - March 15, 2014
Option Year 4, Contract Year 5	March 16, 2014 - March 15, 2015

ARTICLE F.2. DELIVERIES

Satisfactory performance of this 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	on or before the 5th day of the month.
(2)	Quarterly Report on Potency Monitoring	1 electronic	on or before the 5th day after the end of the quarter
(3)	Semi-Annual Report	1 electronic	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	on or before the 15th of the month following the end of the contract year if option years are exercised.
(5)	Final Report	1 electronic, 1 CD	upon contract completion.
(6)	Summary of Salient Results	1 electronic	upon contract completion with final report.
(7)	Roster of Employees Requiring Suitability Investigations	1 hard	within 14 days of the effective date of the contract, and within 15 calendar days of any change
(8)	Information Security Training Report	1 electronic, 1 hard	with the first progress report and subsequent progress reports after any staffing changes
(9)	Reporting of New & Departing Employees	1 hard	within 5 days of any staffing changes

Item	Description	Quantity	Delivery Schedule
(10)	Contractor-Employee Non-Disclosure Agreement(s)	1 hard	within 14 days of the effective date of the contract, and within 15 calendar days of any change
(11)	NIST SP 800-53 Self-Assessment	2 hard	include with any 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 and final upon contract completion

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

Addressee	Deliverable Item No	Quantity
COTR, National Institute on Drug Abuse, DBNBR, 6001 Executive Blvd. Rm. 4261, MSC 9555, Bethesda, MD 20892-9555	1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, & 13	1 electronic &/or 2 hard
Contracting Officer, National Institute on Drug Abuse, NIDA R&D Contracts Management Branch, 6101 Executive Blvd. Rm. 260, MSC 8402, Bethesda, MD 20892-8402	4, 5, 6, 7, 9, 11, 13, &14	1 hard

ARTICLE F.3. LEVEL OF EFFORT

a. In accomplishing the work set forth herein, the Contractor shall provide Labor Hours percent direct labor effort during the period set forth in the PERIOD OF PERFORMANCE Article in SECTION F of this contract. The labor effort Excludes vacation, holiday, and sick leave. This labor effort Excludes subcontractor labor effort. It is estimated that the percent labor effort is constituted as specified below and will be expended approximately as follows:

PERCENT

Labor Category	Year 1	Option Year 2	Option Year 3	Option Year 4	Option Year 5
Professional	Labor Hours				
Support					
Totals					

b. The Contractor shall have satisfied the requirement herein if not less than 95% nor more than 105% of the total direct labor Hours specified herein are furnished.

ARTICLE F.4. CLAUSES INCORPORATED BY REFERENCE, FAR 52.252-2 (FEBRUARY 1998)

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

Hari S. Singh, Ph.D.
Steve W. Gust, Ph.D. (alternate)

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

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

Name	Title
Contractor info	Principal Investigator
	Co-Principal Investigator

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

a. During the course of this contract, the Contractor shall receive requests, or be requested by the NIDA COTR to make certain shipments of cannabis products directly to specified U.S. Government Recipients, Contractors, Government Agencies, or other private research organizations. Upon approval of the NIDA COTR and after appropriate assurances have been verified, 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 price list as set by the National Institute on Drug Abuse. Under no circumstances shall the Contractor bill prices other than those listed as the referenced prices without explicit written directives from NIDA. Prices listed are subject to change and the Contractor will be notified of any changes. A revised price may 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 research organizations/ recipients. 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 COTR may direct from time to time that shipments be made entirely at Government expense or at prices which vary from the standard price list.

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 of Shipments/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--NEGOTIATION of the General Clauses, 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. A copy of this correspondence shall be provided to the Contracting Officer.

Step 2 - Accounts 60 days past due. The Contractor shall turn the account over to a collection agency. A copy of this correspondence shall be provided to the Contracting Officer.

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/CONTRACT FINANCING REQUEST

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.

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