

AWARD/CONTRACT	1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700) ▶	RATING	PAGE OF PAGES 1 60
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2. CONTRACT (Proc. Inst. Ident.) NO. HHSN271201500023C	3. EFFECTIVE DATE 03/23/2015	4. REQUISITION/PURCHASE REQUEST/PROJECT NO. Req # 3722758, RFP No. N01DA-15-7793
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5. ISSUED BY National Institute on Drug Abuse, NIH NIDA R&D Contracts Management Branch 6001 Executive Boulevard, Room 4211, MSC 9559 Bethesda, Maryland 20892-9559	CODE ARH	6. ADMINISTERED BY (If other than Item 5)
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7. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and ZIP Code) The University of Mississippi 100 Barr Hall University, MS 38677-1848 VIN # 1109422 DUNS # 067713560	8. DELIVERY <input type="checkbox"/> FOB ORIGIN <input checked="" type="checkbox"/> OTHER (See below)
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10. SUBMIT INVOICES (4 copies unless otherwise specified) TO THE ADDRESS SHOWN IN	ITEM See Article G.3.
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11. SHIP TO/MARK FOR	CODE	12. PAYMENT WILL BE MADE BY	CODE
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See Section F

See Section G

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: 300N01DA157793 EIN: 646001159 OCC: 25.55 CAN: 158469186 \$1,488,491 (CR)
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15A. ITEM NO.	15B. SUPPLIES/SERVICES	15C. QUANTITY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT
	Production, Analysis, and Distribution of Cannabis and Related Materials Contract Type: Cost Reimbursement (Term/Level-of-Effort) Contract Amount: \$1,488,491 Obligated Amount: \$1,488,491 Period of Performance: March 23, 2015 - March 22, 2016 Ultimate Contract Value: \$68,773,354				

15G. TOTAL AMOUNT OF CONTRACT ▶ \$ 1,488,491

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CONTRACTING OFFICER WILL COMPLETE ITEM 17 (SEALED-BID OR NEGOTIATED PROCUREMENT) OR 18 (SEALED-BID PROCUREMENT) AS APPLICABLE

17. CONTRACTOR'S NEGOTIATED AGREEMENT (Contractor is required to sign this document and return 3 copies to Issuing office.) Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any continuation sheets for the consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the following documents: (a) this award/contract, (b) the solicitation, if any, and (c) such provisions, representations, certifications, and specifications, as are attached or incorporated by reference herein. (Attachments are listed herein.)

18. SEALED-BID AWARD (Contractor is not required to sign this document.)
Your bid 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 to the terms 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 bid, and (b) this award/contract. No further contractual document is necessary. (Block 18 should be checked only when awarding a sealed-bid contract.)

19A. NAME AND TITLE OF SIGNER (Type or Print)
Robin C. Buchannon
Assistant Vice Chancellor for Research & Sponsored Programs

20A. NAME OF CONTRACTING OFFICER
Kenneth E. Goodling, NIDA R&D CMB

19B. NAME OF CONTRACTOR
BY Robin C. Buchannon
(Signature of person authorized to sign)

20B. UNITED STATES OF AMERICA
BY Kenneth E. Goodling
(Signature of Contracting Officer)

19C. DATE SIGNED
3-23-15

20C. DATE SIGNED
3/23/2015

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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

In brief, the objectives are to: (1) cultivate and harvest, process, analyze, store, and distribute cannabis (marijuana) for research; (2) extract cannabis to produce pure and standardized (current Good Manufacturing Practices (cGMP)-grade) cannabis extracts containing varying concentrations of delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD); (3) isolate cGMP and research grade THC, CBD, and other cannabinoids; (4) periodically analyze cannabis extracts, and isolated cannabinoids for authenticity, purity and stability; (5) develop new methods for growing cannabis plants containing high THC, low CBD; high CBD, low THC; and equal strength of CBD and THC; (6) manufacture, analyze, determine stability, store, and supply marijuana cigarettes; and (7) supply cannabis, cannabis extract, other cannabinoids, and marijuana cigarettes to research investigators and/or to the NIDA Drug Supply program upon NIDA authorization.

ARTICLE B.2. ESTIMATED COST - OPTION

- a. The estimated cost of the Base Period of this contract is
- b. If the Government exercises its option pursuant to the OPTION PROVISION Article in SECTION H of this contract, the Government's total estimated cost will be increased as follows:

Base Period and Option Periods:

	Estimated Cost (\$)	
Base Period (Contract Year 1):	est. cost	
Option Period 1 (Contract Year 2):	option year	
Option Period 2 (Contract Year 3):		
Option Period 3 (Contract Year 4):		
Option Period 4 (Contract Year 5):		
Total		
[Base Period and Option Period(s)]:		

Option Quantities:

	Estimated Unit Cost (\$)	Maximum Units Exercised Per Contract Year	Estimated Cost (Maximum Units Exercised Per Contract Year) (\$)
Option Quantity 1a: Cultivation of Cannabis - 1.5 acres (may be exercised a maximum of two times per Contract Year) :			
Base Period (Contract Year 1):	option year		
Option Period 1 (Contract Year 2):			
Option Period 2 (Contract Year 3):			
Option Period 3 (Contract Year 4):			
Option Period 4 (Contract Year 5):			

	Estimated Unit Cost (\$)	Maximum Units Exercised Per Contract Year	Estimated Cost (Maximum Units Exercised Per Contract Year) (\$)
Option Period 4 (Contract Year 5):	option year		
Option Quantity 1b: Cultivation of Cannabis - 6.5 acres (may be exercised a maximum of one time per Contract Year) :			
Base Period (Contract Year 1):	option year		
Option Period 1 (Contract Year 2):	option year		
Option Period 2 (Contract Year 3):			
Option Period 3 (Contract Year 4):			
Option Period 4 (Contract Year 5):			
Option Quantity 1c: Cultivation of Cannabis - 12 acres (may be exercised a maximum of one time per Contract Year) :			
Base Period (Contract Year 1):	option year		
Option Period 1 (Contract Year 2):			
Option Period 2 (Contract Year 3):			
Option Period 3 (Contract Year 4):			
Option Period 4 (Contract Year 5):			
Option Quantity 2a: Production of Cannabis Extract - 10 Kilograms (Kg) (may be exercised a maximum of four times per Contract Year) :			
Base Period (Contract Year 1):	option year		
Option Period 1 (Contract Year 2):			
Option Period 2 (Contract Year 3):			
Option Period 3 (Contract Year 4):			
Option Period 4 (Contract Year 5):			
Option Quantity 2b: Production of Cannabis Extract - 50 Kg (may be exercised a maximum of one time per Contract Year) :			
Base Period (Contract Year 1):	option year		
Option Period 1 (Contract Year 2):			
Option Period 2 (Contract Year 3):			
Option Period 3 (Contract Year 4):			
Option Period 4 (Contract Year 5):			

	Estimated Unit Cost (\$)	Maximum Units Exercised Per Contract Year	Estimated Cost (Maximum Units Exercised Per Contract Year) (\$)
Option Quantity 2c: Production of Cannabis Extract - 100 Kg (may be exercised a maximum of one time per Contract Year) :			
Base Period (Contract Year 1):	option year		
Option Period 1 (Contract Year 2):			
Option Period 2 (Contract Year 3):			
Option Period 3 (Contract Year 4):			
Option Period 4 (Contract Year 5):			
Option Quantity 3: Development and cGMP Manufacturing of Cannabis Extract Formulation Dosage Form (may be exercised a maximum of three times per Contract Year) :			
Base Period (Contract Year 1):	option year		
Option Period 1 (Contract Year 2):			
Option Period 2 (Contract Year 3):			
Option Period 3 (Contract Year 4):			
Option Period 4 (Contract Year 5):			
Option Quantity 4a: Manufacturing of Cannabis (Marijuana) Cigarettes (may be exercised a maximum of five times per Contract Year) :			
Base Period (Contract Year 1):	option year		
Option Period 1 (Contract Year 2):			
Option Period 2 (Contract Year 3):			
Option Period 3 (Contract Year 4):			
Option Period 4 (Contract Year 5):			
Option Quantity 4b: Manufacturing of Cannabis (Marijuana) Cigarettes (may be exercised a maximum of five times per Contract Year) :			
Base Period (Contract Year 1):	option year		
Option Period 1 (Contract Year 2):			
Option Period 2 (Contract Year 3):			
Option Period 3 (Contract Year 4):			
Option Period 4 (Contract Year 5):			
Option Quantity 4c: Manufacturing of Cannabis (Marijuana) Cigarettes (may be exercised a maximum of three times per Contract Year) :			

	Estimated Unit Cost (\$)	Maximum Units Exercised Per Contract Year	Estimated Cost (Maximum Units Exercised Per Contract Year) (\$)
Base Period (Contract Year 1):	option year		
Option Period 1 (Contract Year 2):			
Option Period 2 (Contract Year 3):			
Option Period 3 (Contract Year 4):			
Option Period 4 (Contract Year 5):			
Option Quantity 5: Indoor Cultivation of Cannabis (may be exercised a maximum of one time per Contract Year) :			
Base Period (Contract Year 1):	option year		
Option Period 1 (Contract Year 2):			
Option Period 2 (Contract Year 3):			
Option Period 3 (Contract Year 4):			
Option Period 4 (Contract Year 5):			
Option Quantity 6: Production of Phytocannabinoids (may be exercised a maximum of two times per Contract Year) :			
Base Period (Contract Year 1):	option year		
Option Period 1 (Contract Year 2):			
Option Period 2 (Contract Year 3):			
Option Period 3 (Contract Year 4):			
Option Period 4 (Contract Year 5):			
Option Quantity 7 - Training and Transitional Support (may be exercised one time in the final Contract Year):			
Base Period (Contract Year 1):	option year		
Option Period 1 (Contract Year 2):			
Option Period 2 (Contract Year 3):			
Option Period 3 (Contract Year 4):			
Option Period 4 (Contract Year 5):			
Option Quantity 8: Analysis of Confiscated Marijuana Samples (may be exercised a maximum of five times per Contract Year) :			
Base Period (Contract Year 1):	option year		

	Estimated Unit Cost (\$)	Maximum Units Exercised Per Contract Year	Estimated Cost (Maximum Units Exercised Per Contract Year) (\$)
Option Period 1 (Contract Year 2):	option year		
Option Period 2 (Contract Year 3):			
Option Period 3 (Contract Year 4):			
Option Period 4 (Contract Year 5):			
Option Quantity 9: Materials and Supplies and/or Equipment Purchases (may be exercised a maximum of three times per Contract Year) :			
Base Period (Contract Year 1):	option year		
Option Period 1 (Contract Year 2):			
Option Period 2 (Contract Year 3):			
Option Period 3 (Contract Year 4):			
Option Period 4 (Contract Year 5):			
Total for all Option Quantities [Base Period and Option Period(s)]:			

Ultimate Contract Value [Base Period, Option Periods, and Option Quantities (Maximum Units Exercised Per Contract Year)]:	option year	
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ARTICLE B.3. ADVANCE UNDERSTANDINGS

NIDA reserves the right to have the contracted services benefit NIDA or any other component of NIH. 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 (Facilities and Administrative costs) associated with the Statement of Work shall be at the following predetermined rate as set forth in the University of Mississippi rate agreement with the Department of Health and Human Services (HHS), Division of Cost Allocation (DCA) dated September 12, 2011 for the period from contract award through contract expiration (including Option Period(s) if exercised by NIDA). The rate shall be applicable for the full duration of the contract for the work negotiated under Section C, Article C.1. of this contract.

Rate	Period Covered	Base
Indirect (On-Campus Organized Research)	Contract Inception to Contract Expiration	Modified total direct costs, consisting of all salaries and wages, fringe benefits, materials, supplies,

Rate	Period Covered	Base
		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). Modified total direct costs shall exclude equipment, capital expenditures, charges for patient care, student tuition remission, rental costs of off-site facilities, scholarships, and fellowships as well as the portion of each subgrant and subcontract in excess of \$25,000.

b. Subcontract

To negotiate a cost plus fixed fee type subcontract with Research Triangle Institute, 3040 Cornwallis Road, P.O. Box 12194, Research Triangle Park, NC 27709 for production, analysis, and distribution of cannabis and related materials with amounts not to exceed for the Base Period, Option Periods, and Option Quantities:

Base Period and Option Periods:

	Estimated Cost Not to Exceed (\$)	Fixed Fee Not to Exceed (\$)	Estimated Cost Plus Fixed Fee Not to Exceed (\$)
Base Period (Contract Year 1)	fixed fee; est. cost		\$322,984
Option Period 1 (Contract Year 2)	fixed fee; est. cost; option year		
Option Period 2 (Contract Year 3)			
Option Period 3 (Contract Year 4)			
Option Period 4 (Contract Year 5)			
Total			
[Base Period and Option Period(s)]			

Option Quantities:

	Estimated Cost Not to Exceed (\$)	Fixed Fee Not to Exceed (\$)	Estimated Cost Plus Fixed Fee Not to Exceed (\$)
Option Quantity 2a: Production of Cannabis Extract - 10 Kilograms (Kg) (may be exercised a maximum of four times per Contract Year) :			
Base Period (Contract Year 1):	fixed fee; est. cost; option year		
Option Period 1 (Contract Year 2):			
Option Period 2 (Contract Year 3):			
Option Period 3 (Contract Year 4):			

	Estimated Cost Not to Exceed (\$)	Fixed Fee Not to Exceed (\$)	Estimated Cost Plus Fixed Fee Not to Exceed (\$)
Option Period 4 (Contract Year 5):	<small>fixed fee;est. cost;option year</small>		
Option Quantity 2b: Production of Cannabis Extract - 50 Kg (may be exercised a maximum of one time per Contract Year) :			
Base Period (Contract Year 1):	<small>fixed fee;est. cost;option year</small>		
Option Period 1 (Contract Year 2):			
Option Period 2 (Contract Year 3):			
Option Period 3 (Contract Year 4):			
Option Period 4 (Contract Year 5):			
Option Quantity 2c: Production of Cannabis Extract - 100 Kg (may be exercised a maximum of one time per Contract Year) :			
Base Period (Contract Year 1):	<small>fixed fee;est. cost;option year</small>		
Option Period 1 (Contract Year 2):			
Option Period 2 (Contract Year 3):			
Option Period 3 (Contract Year 4):			
Option Period 4 (Contract Year 5):			
Option Quantity 3: Development and cGMP Manufacturing of Cannabis Extract Formulation Dosage Form (may be exercised a maximum of three times per Contract Year) :			
Base Period (Contract Year 1):	<small>fixed fee;est. cost;option year</small>		
Option Period 1 (Contract Year 2):			
Option Period 2 (Contract Year 3):			
Option Period 3 (Contract Year 4):			
Option Period 4 (Contract Year 5):			
Option Quantity 4a: Manufacturing of Cannabis (Marijuana) Cigarettes (may be exercised a maximum of five times per Contract Year) :			
Base Period (Contract Year 1):	<small>fixed fee;est. cost;option year</small>		
Option Period 1 (Contract Year 2):			
Option Period 2 (Contract Year 3):			
Option Period 3 (Contract Year 4):			
Option Period 4 (Contract Year 5):			

	Estimated Cost Not to Exceed (\$)	Fixed Fee Not to Exceed (\$)	Estimated Cost Plus Fixed Fee Not to Exceed (\$)
Option Quantity 4b: Manufacturing of Cannabis (Marijuana) Cigarettes (may be exercised a maximum of five times per Contract Year) :			
Base Period (Contract Year 1):	fixed fee;est. cost;option year		
Option Period 1 (Contract Year 2):			
Option Period 2 (Contract Year 3):			
Option Period 3 (Contract Year 4):			
Option Period 4 (Contract Year 5):			
Option Quantity 4c: Manufacturing of Cannabis (Marijuana) Cigarettes (may be exercised a maximum of three times per Contract Year) :			
Base Period (Contract Year 1):	fixed fee;est. cost;option year		
Option Period 1 (Contract Year 2):			
Option Period 2 (Contract Year 3):			
Option Period 3 (Contract Year 4):			
Option Period 4 (Contract Year 5):			
Total for all Option Quantities [Base Period and Option Period(s)]:			

Award of the subcontract shall not proceed without the prior written consent of the Contracting Officer upon review of the supporting documentation required by FAR Clause 52.244-2, Subcontracts. After receiving written consent of the subcontract by the Contracting Officer, a copy of the signed, executed subcontract shall be provided to the Contracting Officer. Note: In accordance with FAR 19.704, all subcontracts exceeding \$650,000 will also require a subcontracting plan.

c. **Consultants** Consultant fee(s) to be paid to the following individual(s):

Base Period and each Option Period (if exercised by NIDA) :

Name	Rate Per Day	Number of Days	Travel Costs	Total Cost Including Travel Not to Exceed
% Effort;Consultant Info;Labor Hours;Itemized costs				

Option Quantity 1a - Base Period and each Option Period (if exercised by NIDA):

Name	Rate Per Day	Number of Days	Travel Costs	Total Cost Including Travel Not to Exceed
% Effort;Consultant Info;Labor Hours;Itemized costs				

Option Quantity 1c - Base Period and each Option Period (if exercised by NIDA):

Name	Rate Per Day	Number of Days	Travel Costs	Total Cost Including Travel Not to Exceed
Consultant Info;Labor Hours;Itemized costs				

Option Quantity 2a - Base Period and each Option Period (if exercised by NIDA):

Name	Rate Per Day	Number of Days	Travel Costs	Total Cost Including Travel Not to Exceed
Consultant Info;Labor Hours;Itemized costs				

Option Quantity 2b - Base Period and each Option Period (if exercised by NIDA):

Name	Rate Per Day	Number of Days	Travel Costs	Total Cost Including Travel Not to Exceed
Consultant Info;Labor Hours;Itemized costs				

Option Quantity 2c - Base Period and each Option Period (if exercised by NIDA):

Name	Rate Per Day	Number of Days	Travel Costs	Total Cost Including Travel Not to Exceed
Consultant Info;Labor Hours;Itemized costs				

Option Quantity 8 - Base Period and each Option Period (if exercised by NIDA):

Name	Rate Per Day	Number of Days	Travel Costs	Total Cost Including Travel Not to Exceed
Consultant Info;Labor Hours;Itemized costs				

d. Pre-Contract Costs

Within the dollar limitation set forth under SECTION B, ARTICLE B.2., the Contractor shall be entitled to reimbursement for costs incurred during the period March 16, 2015 through March 23, 2015 in an amount not to exceed [Itemized costs] which if incurred after this contract had been entered into, would have been reimbursable under the provisions of this contract. Reimbursement is limited to direct costs and the associated Facilities & Administrative (F&A) costs. Note: Costs for equipment purchases are not permitted.

e. 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.

f. DEA and FDA Registrations

For the duration of the contract, the Contractor and/or its subcontractor(s) agrees to maintain, at no direct cost to the contract, its required Drug Enforcement Administration (DEA) registrations for working with scheduled drugs. In addition, the Contractor and/or its subcontractor(s) agrees to maintain, at no direct cost to the contract, its Food and Drug Administration (FDA) registration as a pharmaceutical manufacturing facility.

g. Cost-Reimbursement of Research Substances for Non-Federally Supported Projects

Pursuant to Department of Health and Human Services (HHS) policy published May 21, 1999, marijuana for non-Federally funded research is to be provided on a cost-reimbursement basis. NIDA intends to implement collection of fees for marijuana once HHS and the National Institutes of Health (NIH) develop updated policies and transactional procedures on the specifics regarding cost-reimbursement of research substances for non-Federally supported projects. These policies and procedures may significantly impact the timing, mechanisms, and recipient of any collected fees. NIDA shall modify the contract to reflect these policies and procedures upon their adoption by HHS and NIH.

h. 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. HHSN271201500023C .

NIDA Reference No. N01DA-15-7793 .

ARTICLE B.4. 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. Conferences and Meetings (see Section H, Article H.23.);
2. Food for Meals, Light Refreshments, and Beverages;
3. *Promotional Items [includes, but is not limited to: clothing and commemorative items such as pens, mugs/cups, folders/folios, lanyards, and conference bags that are sometimes provided to visitors, employees, grantees, or conference attendees];*
4. Acquisition, by purchase or lease, of any interest in real property;
5. Special rearrangement or alteration of facilities;
6. Purchase or lease of **any** item of general purpose office furniture or office equipment regardless of dollar value. (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.);

7. Travel to attend general scientific meetings;
8. Foreign travel, see paragraph b. below;
9. Consultant costs in excess of \$250 per day;
10. Subcontracts requiring consent under FAR 52.244-2;
11. Patient care costs;
12. Accountable Government Property (defined as non-expendable personal property with an acquisition cost of \$1,000 or more) and "sensitive items" (defined as items of personal property (supplies and equipment that are highly desirable and easily converted to personal use), regardless of acquisition value; and
13. Printing Costs (as defined in the Government Printing and Binding Regulations).

b. Travel Costs

1. Domestic Travel

Total expenditures for domestic travel (transportation, lodging, subsistence, and incidental expenses) incurred in direct performance of this contract, exclusive of subcontracting, shall not exceed [option year] without the prior written approval of the Contracting Officer. In the event that Option Period(s) are exercised, the not-to-exceed amount shall be increased by [option year] for Option Period 1 (Contract Year 2); [option year] for Option Period 2 (Contract Year 3); [option year] for Option Period 3 (Contract Year 4); and [option year] for Option Period 4 (Contract Year 5).

In the event that Option Quantit(ies) are exercised, the not-to-exceed amount shall be increased by [option year] per Contract Year for Option Quantity 3 (may be exercised a maximum of three times per Contract Year); [option year] per Contract Year for Option Quantity 4a (may be exercised a maximum of five times per Contract Year); [option year] per Contract Year for Option Quantity 4b (may be exercised a maximum of five times per Contract Year); [option year] per Contract Year for Option Quantity 4c (may be exercised a maximum of three times per Contract Year); and by [option year] per Contract Year for Option Quantity 7 (may be exercised a maximum of one time in the final Contract Year).

2. Foreign Travel

Total expenditures for foreign travel (transportation, lodging, subsistence, and incidental expenses) incurred in direct performance of this contract shall not exceed \$0 without the prior written approval of the Contracting Officer.

3. The Contractor shall invoice and be reimbursed for all travel costs in accordance with Title 2 of CFR, Part 220-Cost Principles for Educational Institutions (OMB Circular A-21).

[The remainder of this page is intentionally left blank.]

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. STATEMENT OF WORK

I. Background Information and Objectives

A. Background Information:

The primary purpose of this contract is to provide materials to support research on marijuana (cannabis) and its constituents. 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 and this present procurement is a continuation of that effort.

Currently, due to the requirements of the 1961 Single Convention on Narcotic Drugs, there is a single Government entity that controls the production and distribution of marijuana for medical and research purposes. The US Drug Enforcement Agency (DEA) has licensed a contractor of the National Institute on Drug Abuse (NIDA) to grow, process, and distribute marijuana on behalf of the United States (U.S.) Government. In addition, chemical constituents of marijuana, such as delta-9-tetrahydrocannabinol (THC) and other cannabinoids are difficult to obtain commercially in sufficient quantities or are very expensive to purchase for research. Therefore, NIDA has been providing the research community with standardized samples of cannabis, various cannabinoids and other drugs of abuse for basic and clinical research through its Drug Supply Program.

B. Objectives:

The main objectives of this contract are to: (1) cultivate and harvest, process, analyze, store, and distribute cannabis (marijuana) for research; (2) extract cannabis to produce pure and standardized (current Good Manufacturing Practices (cGMP)-grade) cannabis extracts containing varying concentrations of delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD); (3) isolate cGMP and research grade THC, CBD, and other cannabinoids; (4) periodically analyze cannabis extracts, and isolated cannabinoids for authenticity, purity and stability; (5) develop new methods for growing cannabis plants containing high THC, low CBD; high CBD, low THC; and equal strength of CBD and THC; (6) manufacture, analyze, determine stability, store, and supply marijuana cigarettes; and (7) supply cannabis, cannabis extract, other cannabinoids, and marijuana cigarettes to research investigators and/or to the NIDA Drug Supply program upon NIDA authorization.

II. Services to Be Performed

A. General Requirements:

Independently, and not as an agent of the Government, the Contractor shall be required to furnish all necessary services, qualified personnel, materials, equipment, and facilities, not otherwise provided by the Government, as needed to perform the requirements specified below:

The Contractor shall produce cannabis, cannabis extract, other cannabis-derived materials, and cannabis cigarettes for basic and clinical research, their quantitative and qualitative analysis, stability determination, and storage and shipment for research. Cannabis is used in a large variety of research projects and this contract serves as the only legal source of such material in the U.S. The Contractor shall grow sufficient quantities of cannabis to meet anticipated needs as directed by the NIDA Contracting Officer's Representative (COR), followed by careful quantitative analysis and storage prior to marijuana cigarette manufacturing and/or shipment for research. NIDA supplies research investigators with cannabis and its main psychoactive component, delta-9-THC, and other non-psychoactive components such as cannabinoil (CBN), CBD, cannabichromene (CBC), cannabigerol (CBG), other cannabinoids, and marijuana cigarettes.

In order to meet present and anticipated needs for phytocannabinoids, the Contractor shall extract cannabis to isolate pure THC and other cannabinoids, obtain cannabis extract of known potencies, manufacture marijuana cigarettes of varying potencies, and provide purified materials and marijuana cigarettes for research and/or to the NIDA Drug Supply program, as directed by the COR. Cannabis and cannabis cigarettes provided through this contract are not available commercially or through any other legal sources. Similarly, cannabinoids such as THC, CBD and other

minor cannabinoids are either unavailable commercially or if available, are not in sufficient quantities and/or are very expensive.

The Contractor shall grow cannabis, produce research and cGMP-grade cannabis and cannabis cigarettes, and maintain a stock of cannabis preparations such as cigarettes of varying potencies, various cannabinoids, and cannabis extracts for distribution to fulfill requirements set forth below. The Contractor shall analyze cannabis samples, and cigarettes for cannabinoid contents. All pertinent Food and Drug Administration (FDA) and DEA requirements (e.g., cGMP) must be met for the cannabis 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.

All work under this contract shall be monitored by the Government COR who is defined in Section G of this contract.

B. Specific Requirements:

Specifically, the Contractor shall perform the following:

1. Produce and maintain an inventory of cannabis of different varieties as required by NIDA. More specifically, the Contractor shall:

a. Upon exercise of Option Quantity 1 (a, b, and/or c), plant, grow, and harvest cGMP-grade cannabis (composed predominantly of but not limited to Mexican and Colombian varieties and occasionally, Indian, Turkish, or other varieties) for basic and clinical research. The Contractor shall carry out harvesting 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 Contractor shall dry the collected material in an efficient and expeditious manner and place it in the storage. The Contractor shall properly dispose of all waste materials.

Note: The current inventory of cannabis under the predecessor contract shall be available for initial use under this contract. Upon exercise of Option Quantity 5, the Contractor shall grow indoor a minimum quantity of 10 Kg of cGMP-grade cannabis of varying cannabinoids contents as determined by the COR.

b. Determine the major cannabinoids contents in harvested and inventoried cannabis by gas liquid chromatography (GLC) and/or any other suitable technique. Minimally, this will require the quantification of delta-9-THC, CBD, CBC, CBN, delta-8-THC, and CBG. Some samples may require analysis for THC acids A and B. The Contractor shall properly dispose of all waste materials.

c. 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. The Contractor shall properly dispose of all waste materials.

2. Extract cannabis to produce approximately 1 Kg of cGMP-grade marijuana extract of known CBD and THC contents as required by the COR.

If additional cannabis extract is required beyond the 1 Kg limit, the Contractor shall produce additional cannabis extract (10 Kg, 50 Kg, and/or 100 Kg) upon the exercise of the respective Option Quantity 2 (a, b, and/or c). The Contractor shall properly dispose of all waste materials.

The Contractor shall quantitatively analyze samples of cannabis extract for determining the THC, CBD and other cannabinoids contents, and upon NIDA authorization supply cannabis extract of known potency and specifications to the NIDA Drug Supply inventory.

3. Extract cannabis to isolate 200 g of research grade (>95%) delta-9-THC, and provide pure delta-9-THC to the NIDA Drug Supply inventory upon COR authorization. Upon exercise of Option Quantity 6, the Contractor shall produce cGMP-grade delta-9-THC and other phytocannabinoids.

4. Maintain the existing stock of marijuana cigarettes for use in research. The Contractor must maintain all stock items on a first-in, first-out (FIFO) inventory system, unless otherwise designated by the COR. If at any time during the course of this contract the Contractor receives a request that would cause the stock to fall below 100 canisters, the Contractor shall notify the COR.

The Contractor shall also:

- a. Develop and manufacture standardized marijuana cigarettes within a range of specified delta-9-THC, or CBD, or both delta-9-THC and CBD contents and placebo upon the exercise of Option Quantity 4 as required by NIDA.
- b. Prepare, preferably by hand-rolling, a small batch of marijuana cigarettes containing varying concentrations of THC or CBD or both as required by NIDA upon exercise of Option Quantity 4c. More specifically, the Contractor shall:
 - i. Ascertain strength of inventoried marijuana cigarettes by their periodic analysis at 6-month intervals or as required by the COR and update its analytical data sheets.
 - ii. Carry out stability analyses on inventoried marijuana cigarettes at various time periods (such as 3, 6, 9, 12, 24, 36, 48 and 60 months) and temperature, or as directed by the COR.
 - iii. Perform quality control testing of newly and previously manufactured marijuana cigarettes on a regular basis to maintain their integrity.
 - iv. Ship marijuana cigarettes to research investigators as required by NIDA. The Contractor shall enclose analytical data sheets with each shipment or as specified by the COR.
 - v. Maintain a secure and video-monitored quality control shipping facility while having an expertise in handling and shipping of marijuana and marijuana cigarettes.
 - vi. Maintain supply and shipment records of all shipments in NIDA Drug Inventory Supply Control System (DISCS), a NIDA database.

Note: NIDA maintains this extensive inventory and shipment tracking system on an ORACLE Database system with Visual Basic on NIDA's Local Area Network. The Contractor must monitor exact quantities on-hand, adjust inventory of new compounds, re-purifications, and reductions in amount following shipment, produce shipping documents, and provide tracking of shipping orders at the Contractor's site. Employees of the Contractor who will have access to DISCS must take requisite security-related trainings and meet security clearance requirements.

5. Provide an adequate DEA approved storage facility and store cannabis, cannabis extract, cannabis (marijuana) cigarettes, and isolated pure cannabinoids at an optimal temperature. More specifically, the Contractor shall:
 - a. Store available marijuana bulk plant materials including previous crops, marijuana cigarettes, and marijuana extracts in appropriate containers at 75°F or at a suitable temperature to minimize chemical degradation for low THC, high THC, low CBD, high CBD, and equal THC and CBD containing materials. The Contractor shall maintain a minimum stock of 250 Kg of bulk plant materials and have storage capacity of approximately 700 Kg of such materials.
 - b. Store and keep records of all materials in accordance with the current DEA requirements. The Contractor shall store cannabis in a secure room(s) reserved for that purpose, and specially equipped to provide necessary security. Local DEA agents will determine the exact type of security required.
 - c. Maintain a database system containing all pertinent analytical data on individual sample analyses.
6. Carry out stability analyses at various time periods (3, 6, 9, 12, 24, 36, 48, and 60 months) or as directed by the COR, on newly harvested bulk cannabis, marijuana cigarettes, cannabis extracts, and isolated cannabinoids including THC, CBD, and other cannabinoids to assure purity and strength.
7. Employ the NIDA Drug Inventory Supply Control System (DISCS) database for supply and shipment records of cannabis, cannabinoids, cigarettes, and any other preparations of cannabis that are shipped by the Contractor.
8. Prepare and submit monthly progress reports to the COR on all activities in the project including preparation, analysis, and shipping of marijuana, marijuana cigarettes, marijuana extracts, and related products.
9. Prepare a new document or a document as an addendum to the NIDA Drug Master File (DMF) on marijuana and marijuana cigarettes following DMF guidelines for submission to the FDA (three hard bound copies as required by FDA) when required by the COR, or after growing, harvesting, analyzing, and obtaining appropriate information

and relevant data on new batches of cannabis, cGMP-grade cannabis extract, THC and CBD produced, and newly manufactured marijuana cigarettes.

10. Upon NIDA authorization, dispose of contaminated and/or unusable cannabis plant materials, marijuana cigarettes, or any other cannabis materials in accordance with appropriate DEA regulations.

11. Perform analysis of confiscated marijuana samples upon exercise of Option Quantity 8.

C. Option Period 1 (Contract Year 2) Through Option Period 4 (Contract Year 5):

The Government reserves the right to exercise Option Periods 1, 2, 3, and 4 to extend the contract for an additional year at the end of each Contract Year if there is a continued need for the services performed and if the Contractor's performance has been satisfactory. The services provided by the Contractor in Option Period 1, Contract Year 2 through Option Period 4, Contract Year 5 of the contract, if exercised, shall be identical to the services described in the Base Period, Contract Year 1. The Government will evaluate the progress of this contract 3 months before the end of each Contract Year and decide within 30 days whether to exercise the next Option Period.

D. Option Quantities:

Option Quantity 1 - Cultivation of Cannabis:

Upon exercise of this Option Quantity (1a., 1b., or 1c.), respectively, the Contractor shall cultivate, grow, harvest, analyze, and store research grade cannabis, as specified in detail under the Statement of Work (SOW) in one of the following amounts as required by NIDA:

Option Quantity 1a: 1.5 acres (may be exercised a maximum of two times per Contract Year)

Option Quantity 1b: 6.5 acres (may be exercised a maximum of one time per Contract Year)

Option Quantity 1c: 12 acres (may be exercised a maximum of one time per Contract Year)

NIDA may exercise individual Option Quantities as and when warranted during the period of performance of the contract up to the maximum quantities indicated above, not to exceed 12 acres of cultivation per Contract Year. NIDA shall provide notification of intent to exercise an Option Quantity under the SOW to the Contractor on or before March 15 of the year in which the Option Quantity is to be exercised.

Option Quantity 2 - Production of Cannabis Extract:

Upon exercise of this Option Quantity (2a., 2b., or 2c.), respectively, the Contractor shall extract cannabis and produce cGMP-grade cannabis extract (high CBD, low THC; high THC, low CBD; and equal ratio of CBD and THC), or as required by the COR and perform all necessary testing as described elsewhere in the SOW.

The Contractor shall prepare the extracts in one of the following amounts as required by NIDA:

Option Quantity 2a: 10 Kg (may be exercised a maximum of four times per Contract Year)

Option Quantity 2b: 50 Kg (may be exercised a maximum of one time per Contract Year)

Option Quantity 2c: 100 Kg (may be exercised a maximum of one time per Contract Year)

NIDA may exercise individual Option Quantities as and when warranted during the period of performance of the contract up to the maximum quantities indicated above.

Option Quantity 3 - Development and cGMP Manufacturing of Cannabis Extract Formulation Dosage Form:

Upon exercise of this Option Quantity, the Contractor shall:

1. Develop timelines, including milestones, and related budgets for the pre-formulation and formulation studies, including analytical and validation methods to be used in the formulation development, stability analyses, and manufacturing processes for bulk production of specified quantities of acceptable drug dosage form of cannabis extract of known cannabinoid strengths (THC and CBD).

2. Develop a formulation for CBD-rich extract to contain specific level(s) of CBD and THC in consultation with NIDA, a scientific advisory panel, and FDA under cGMP regulations. The Contractor shall also establish and update if needed a new NIDA Drug Master File on this drug dosage form to support Investigational New Drug (IND) research. Work to be conducted by the Contractor will include the following: (1) validation of drug dosage form formulation process; (2) development and validation of analytical methods for determination of cannabinoids contents of new drug dosage form, particularly CBD and THC contents, and (3) conducting stability analyses on this formulation at various temperatures, such as room temperature, refrigerator and freezer temperatures for at least 6 months, and maintaining stability samples for continued monitoring for 2 years.

3. Manufacture, analyze, store, and distribute drug dosage form of cannabis extract of known cannabinoid strength for clinical and non-clinical research as authorized by the COR. The manufacturing of two (2) batches of this drug dosage form and its placebo will be authorized under cGMP regulations. The typical batch size should be 10,000 units of, capsules/ampoules/or any other developed drug dosage form of various specified THC and CBD contents and/or ratio, unless otherwise specified by the COR. The batches may differ in cannabinoid content and/or ratio of THC and CBD as determined by NIDA.

NIDA may exercise this Option Quantity as and when warranted during the period of performance of this contract up to a maximum of three times per Contract Year.

Option Quantity 4 - Manufacturing of Cannabis (Marijuana) Cigarettes:

Upon exercise of this Option Quantity (4a., 4b., or 4c.), the Contractor shall manufacture cGMP-grade cannabis cigarettes, ascertain physical and chemical specifications, check purity and any other required specifications, create data sheets, and store and distribute the cigarettes upon NIDA authorization as described elsewhere in the SOW.

The Contractor shall manufacture the cigarettes in the following amounts and specifications as required by NIDA:

Option Quantity 4a: (may be exercised a maximum of five times per Contract Year)
25,000 Standardized marijuana cigarettes, THC content as specified by the COR.

Option Quantity 4b: (may be exercised a maximum of five times per Contract Year)
25,000 Standardized marijuana cigarettes, CBD content as specified by the COR.

Option Quantity 4c: (Note: The Contractor may manufacture these cigarettes by hand-rolling) (may be exercised a maximum of three times per Contract Year):
5,000 standardized marijuana cigarettes containing a high concentration of delta-9-THC, or CBD or both (greater than 5.0%) or as required by the COR.

NIDA may exercise individual Option Quantities as and when warranted during the period of performance of the contract up to the maximum quantities indicated above.

Option Quantity 5 - Indoor Cultivation of Cannabis:

Upon exercise of this Option Quantity, the Contractor shall:

- a. Grow, harvest, analyze, and store a minimum quantity of 10 kg of cGMP-grade cannabis indoor. The COR will determine various cannabinoids contents of cannabis to be grown.
- b. Determine the major cannabinoids contents in harvested cannabis by GLC and/or any other suitable methods. Minimally this will require the quantification of delta-9-THC, CBD, CBC, CBN, delta-8-THC, and CBG. Some samples may require analysis of THC acids A and B. Disposal of all waste materials is inclusive.
- c. Reanalyze samples of indoor crops to determine viability of samples. Generally this will require one analysis per batch or storage container every 3 months. Disposal of all waste materials is inclusive to this task.

NIDA may exercise this Option Quantity as and when warranted during the period of performance of the contract up to a maximum of one time per Contract Year.

