UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 8-K

Current Report
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): September 19, 2018

OPIANT PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-38193**	**46-4744124**
(State or other jurisdiction of incorporation)	(Commission File Number	(IRS Employer Identification No.)

201 Santa Monica Boulevard, Suite 500 **Santa Monica, CA**	**90401**
(Address of Principal Executive Offices)	(Zip Code)

(310) 598 5410
Registrant's telephone number, including area code

(Former name or former address if changed since last report,)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐
If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 1.01 Entry into a Material Definitive Agreement.

On September 19, 2018, Opiant Pharmaceuticals, Inc. (the "**Company**") entered into a contract ("**Contract**") with the Biomedical Advanced Research and Development Authority ("**BARDA**"), which is part of the U.S. Health and Human Services Office of the Assistant Secretary for Preparedness and Response, to accelerate the Company's development of OPTN003, its lead product candidate. OPTN003, nasal nalmefene, is a potent, long-acting opioid antagonist currently in development for the treatment of opioid overdose. The Contract will provide potential funding up to a maximum of approximately $4.6 million and cover activities related to a potential New Drug Application submission for OPTN003 with the Food and Drug Administration. The Contract will provide approximately $611,000 for the project through September 30, 2019, with the balance to be funded over the following two years, subject to satisfactory project progress, availability of funds and certain other conditions.

A copy of the Contract is attached to this Current Report on Form 8-K and is incorporated herein by reference. The description of the Contract provided herein is qualified in its entirety by reference to the terms of the Contract as set forth in Exhibit 10.86.

Item 8.01 Other Events

On September 14, 2018, the Company and Adapt Pharma, Inc. ("**Adapt**") received notice from Perrigo UK FINCO Limited Partnership ("**Perrigo**"), pursuant to 21 U.S.C. ß 355(j)(2)(B)(ii) (the "**Notice Letter**"), that Perrigo had filed an Abbreviated New Drug Application ("**ANDA**") with the United States Food and Drug Administration ("**FDA**") seeking regulatory approval to market a generic version of NARCAN® (naloxone hydrochloride) Nasal Spray before the expiration of U.S. Patent Nos. 9,211,253 (the "'**253 Patent**"), 9,468,747 (the "'**747 Patent**"), 9,561,177 (the "'**177 Patent**"), 9,629,965 (the "'**965 Patent**") and 9,775,838 (the "'**838 Patent**"). The '253, '747, '177, '965 and '838 patents are listed with respect to NARCAN® in the FDA's Approved Drug Products with Therapeutic Equivalents Evaluation publication (commonly referred to as the "**Orange Book**") and expires on March 16, 2035. Perrigo's Notice Letter asserts that its generic product will not infringe the '253, '747, '177, '965 and '838 patents or that the '253, '747, '177, '965 and '838 patents are invalid or unenforceable. Pursuant to an Exclusive License Agreement, entered into on December 14, 2014, as amended, the Company has exclusively licensed the '253, '747, '177, '965 and '838 patents to Adapt. The Company and Adapt are evaluating Perrigo's Notice Letter.

The Company has full confidence in its intellectual property portfolio related to NARCAN®. The Company and Adapt may receive additional Notice Letters from other companies seeking to market generic versions of NARCAN® in the future and, after evaluation, Adapt may commence patent infringement lawsuits against such companies.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
10.86*	Contract between the Company and Biomedical Advanced Research and Development Authority dated September 19, 2018.

*Confidential treatment has been requested with respect to certain portions of this exhibit. Omitted portions have been filed separately with the SEC.

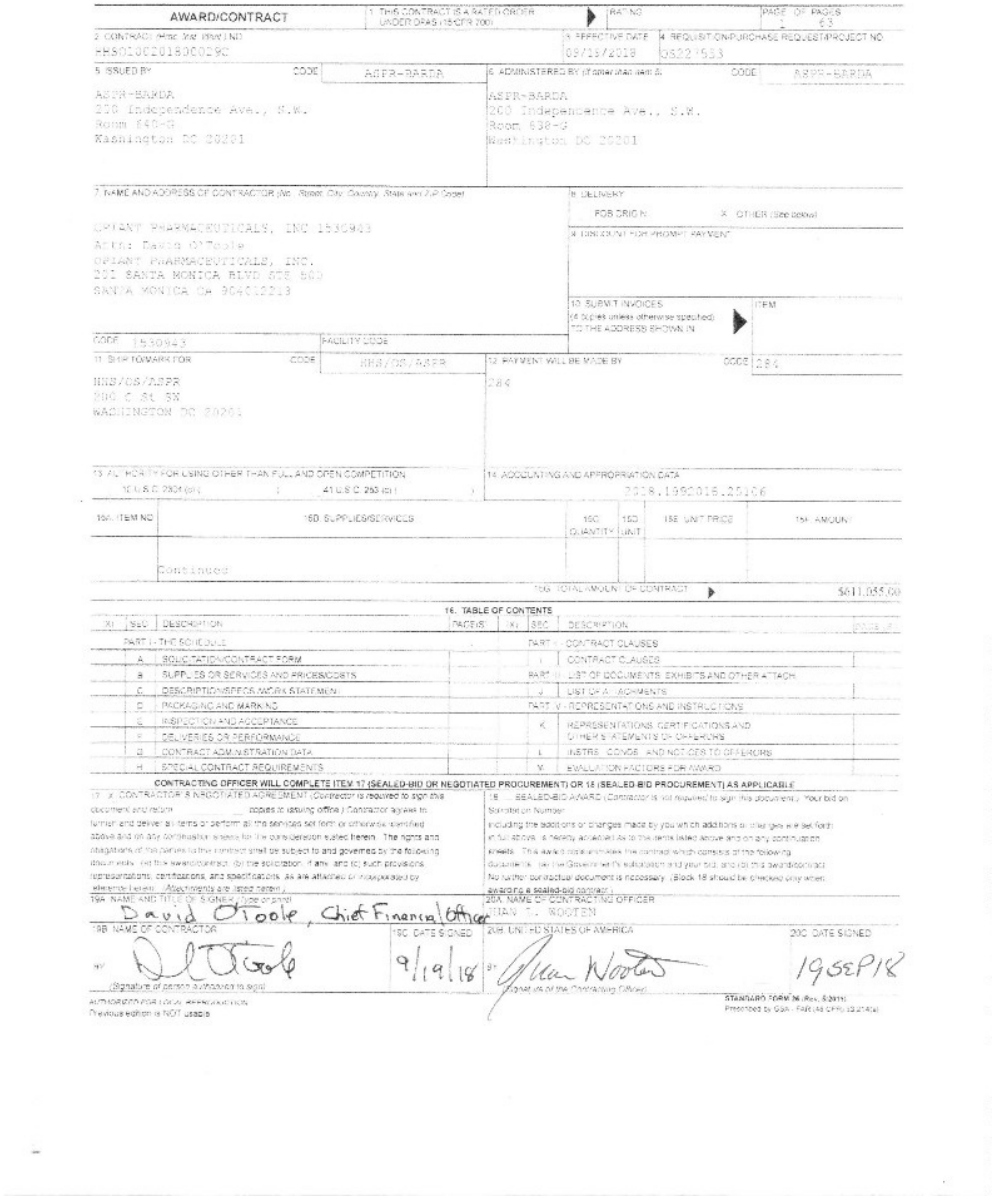
SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this Report to be signed on its behalf by the undersigned hereunto duly authorized.

OPIANT PHARMACEUTICALS, INC.

Dated: September 20, 2018 By: /s/ David O'Toole

Name: David D. O'Toole
Title: Chief Financial Officer



AWARD/CONTRACT

1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)

RATING

PAGE OF PAGES 1 63

2. CONTRACT (Proc. Inst. Ident.) NO. HHSO100201800029C

3. EFFECTIVE DATE 09/19/2018

4. REQUISITION/PURCHASE REQUEST/PROJECT NO. 0322533

5. ISSUED BY CODE ASPR-BARDA

ASPR-BARDA
200 Independence Ave., S.W.
Room 640-G
Washington DC 20201

6. ADMINISTERED BY (If other than item 5) CODE ASPR-BARDA

ASPR-BARDA
200 Independence Ave., S.W.
Room 638-G
Washington DC 20201

7. NAME AND ADDRESS OF CONTRACTOR (No., Street, City, County, State and ZIP Code)

ORIANT PHARMACEUTICALS, INC 1530943
Attn: David OToole
ORIANT PHARMACEUTICALS, INC.
201 SANTA MONICA BLVD STE 500
SANTA MONICA CA 904012213

8. DELIVERY
FOB ORIGIN X OTHER (See below)

9. DISCOUNT FOR PROMPT PAYMENT

10. SUBMIT INVOICES (4 copies unless otherwise specified) TO THE ADDRESS SHOWN IN ITEM

CODE 1530943 FACILITY CODE

11. SHIP TO/MARK FOR CODE HHS/OS/ASPR

HHS/OS/ASPR
200 C St, SW
WASHINGTON DC 20201

12. PAYMENT WILL BE MADE BY CODE 284

284

13. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION
10 U.S.C. 2304(c)( ) 41 U.S.C. 253 (c)( )

14. ACCOUNTING AND APPROPRIATION DATA
2018.1990018.20106

15A. ITEM NO	15B. SUPPLIES/SERVICES	15C. QUANTITY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT
	Consignee				

15G. TOTAL AMOUNT OF CONTRACT $611,055.00

16. TABLE OF CONTENTS

(X)	SEC.	DESCRIPTION	PAGE(S)	(X)	SEC.	DESCRIPTION	PAGE(S)
		PART I - THE SCHEDULE				PART II - CONTRACT CLAUSES	
	A	SOLICITATION/CONTRACT FORM			I	CONTRACT CLAUSES	
	B	SUPPLIES OR SERVICES AND PRICES/COSTS				PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACH.	
	C	DESCRIPTION/SPECS./WORK STATEMENT			J	LIST OF ATTACHMENTS	
	D	PACKAGING AND MARKING				PART IV - REPRESENTATIONS AND INSTRUCTIONS	
	E	INSPECTION AND ACCEPTANCE			K	REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS	
	F	DELIVERIES OR PERFORMANCE			L	INSTRS., CONDS., AND NOTICES TO OFFERORS	
	G	CONTRACT ADMINISTRATION DATA			M	EVALUATION FACTORS FOR AWARD	
	H	SPECIAL CONTRACT REQUIREMENTS					

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

17. X CONTRACTOR'S NEGOTIATED AGREEMENT (Contractor is required to sign this document and return ___ 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 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 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)
David OToole, Chief Financial Officer

20A. NAME OF CONTRACTING OFFICER
JUAN T. WOOTEN

19B. NAME OF CONTRACTOR

19C. DATE SIGNED 9/19/18

20B. UNITED STATES OF AMERICA

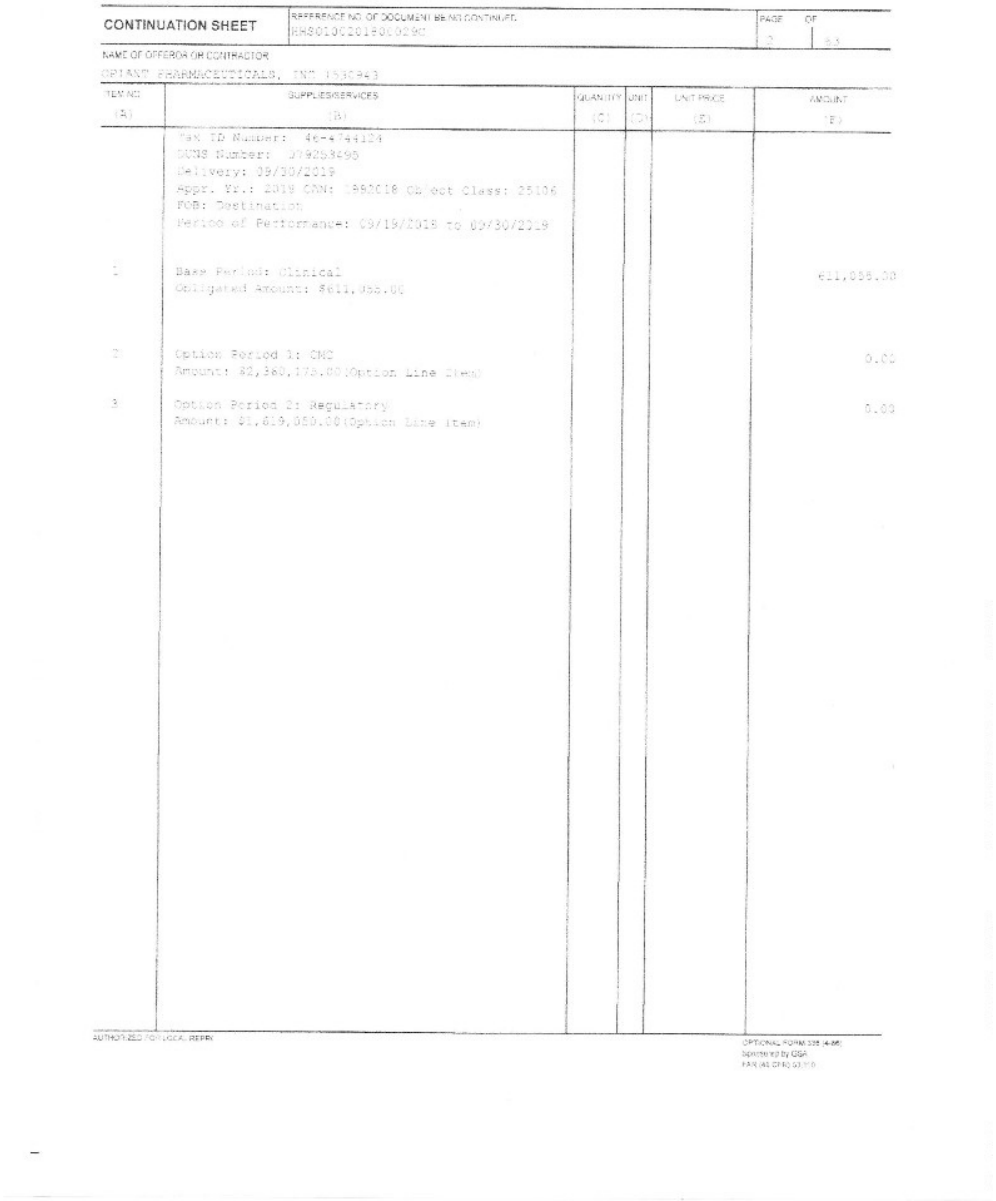
20C. DATE SIGNED 19SEP18

(Signature of person authorized to sign) (Signature of the Contracting Officer)

AUTHORIZED FOR LOCAL REPRODUCTION
Previous edition is NOT usable

STANDARD FORM 26 (Rev. 8/2011)
Prescribed by GSA - FAR (48 CFR) 53.214(a)

* Certain confidential information contained in this document, marked [***], is filed separately with the Securities and Exchange Commission.



CONTINUATION SHEET	REFERENCE NO. OF DOCUMENT BEING CONTINUED: HHS0100201901029C	PAGE 2 OF 5

NAME OF OFFEROR OR CONTRACTOR

OPTANIX PHARMACEUTICALS, INC 153C943

ITEM NO (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	Tax ID Number: 46-4744124 DUNS Number: 079253295 Delivery: 09/30/2019 Appr. Yr.: 2019 CAN: 390018 Object Class: 25106 FOB: Destination Period of Performance: 09/19/2019 to 09/30/2019				
1	Base Period: Clinical Obligated Amount: $611,056.00				$611,056.00
2	Option Period 1: CMC Amount: $2,360,175.00(Option Line Item)				0.00
3	Option Period 2: Regulatory Amount: $1,819,050.00(Option Line Item)				0.00

AUTHORIZED FOR LOCAL REPRO

OPTIONAL FORM 336 (4-86)
Prescribed by GSA
FAR (48 CFR) 53.110

* Certain confidential information contained in this document, marked [***], is filed separately with the Securities and Exchange Commission.

EXHIBIT 10.86

CONFIDENTIALTREATMENT REQUESTED

CONFIDENTIAL PORTIONS OF THIS DOCUMENT HAVE BEEN REDACTED AND HAVE BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION

Contents

* Certain confidential information contained in this document, marked [***], is filed separately with the Securities and Exchange Commission.

PART I – THE SCHEDULE

SECTION B – SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

* Certain confidential information contained in this document, marked [***], is filed separately with the Securities and Exchange Commission.

The goal of this effort is to reformulate Nalmefene, an FDA approved drug for opioid overdose, for intranasal delivery using Intravail, a proprietary absorption enhancer. Opioids have been identified as a public health emergency. Preliminary data in a pilot study utilizing healthy volunteers demonstrated that intranasal Nalmefene with Intravail, produced peak plasma concentrations as rapidly as parenteral (intramuscular) administration, but with significantly longer half-life than naloxone, the only other FDA approved drug for opioid overdose. Nalmefene is attractive because it would most likely only require a single administration to treat victims with an overdose due to its longer half-life compared to naloxone. Opiant has received a grant from NIDA to perform formulation development and conduct the clinical studies for this product. BARDA funded activities include human factors studies to evaluate the ease of use of the intranasal device, registration batch manufacture and stability and NDA preparation and filing.

The work to be performed during the Base Period represents a non-severable discrete work segment. Each Option work period further represents a non-severable discrete work segment. The work in the Base Period and each Option period will be fully funded from funds that are available for obligation at the time of the initial award (Base Period) and at the time of the award of each Option period.

ARTICLE B.2. BASE PERIOD [***]

a. The total estimated cost of the base period of the contract excluding fee is **[***].**

b. The total fixed fee for the base period of performance is **[***].**

c. The total estimated cost of the base period of the contract, CLIN 0001, represented by the sum of the total estimated cost plus fixed fee is **[***].** The government will not be responsible for any Contractor-incurred costs that exceed this amount unless a modification to the contract is signed by the Contracting Officer which expressly increases this amount.

d. The Contractor shall maintain records of all contract costs and such records shall be subject to FAR 52.215-2 (Oct 2010), Audit and Records-Negotiation, and Health and Human Services Acquisition Regulation (HHSAR) 352.242-74, Final Decisions on Audit Findings, incorporated by reference into this contract in SECTION I.

CLIN	Estimated Period of Performance	Supplies/Services	Total Estimated Cost	Fixed Fee	Total Estimated Cost Plus Fixed Fee
1	[***]	Clinical - Human Use Characteristics	[***]	[***]	[***]

ARTICLE B.3. OPTION PRICES

Pursuant to FAR 52.217-9, Option to Extend the Term of the Contract (Mar 2000), set forth in full in ARTICLE I.3 of this contract, the government may, by unilateral contract modification, require the Contractor to perform discrete portions of additional work as specified in the Statement of Work.

Unless the government exercises one or more optional CLINs, the contract consists only of the base work specified in the Statement of Work as defined in SECTIONS C and F, with estimated costs set forth in ARTICLE B.2 of the contract.

CLIN	Option	Est. Period of Performance	Supplies/ Services	Total Estimated Cost	Fixed Fee	Total Estimated Cost Plus Fixed Fee
2	1	[***]	CMC Registration Batch Manufacture	[***]	[***]	[***]
3	2	[***]	Regulatory NDA	[***]	[***]	[***]

ARTICLE B.4. LIMITATIONS APPLICABLE TO DIRECT COSTS

a. Items Unallowable Unless Otherwise Provided

Notwithstanding the clause FAR 52.216-7, Allowable Cost and Payment, incorporated in this contract, unless authorized in writing by the Contracting Officer in the form of a Contracting Officer Authorization (COA), 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, subject to limitation under Article B.4.b.1;

5. Foreign travel;

6. Subcontractor and/or Consultant costs;

7. Patient care costs;

8. 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” regardless of acquisition value (Section J, Attachment 6).

9.Printing Costs (as defined in the government Printing and Binding Regulations).

10.Light Refreshment and Meal Expenditures are not authorized.

11.Costs for meeting room or conference space used for face to face meetings with United States government (USG) staff in the performance of this contract at Government or Contractor facilities are not authorized.

* Certain confidential information contained in this document, marked [***], is filed separately with the Securities and Exchange Commission.

b. Travel Costs

1. Total expenditures for all travel (transportation, lodging, subsistence, and incidental expenses) incurred by the Prime Contractor in direct performance of this contract during the base period shall not exceed **$2,400** without the prior written approval of the Contracting Officer. Cost must be consistent with FAR 52.247-63 – Preference for U.S. - Flag Air Carriers.
2. The Contactor shall invoice and be reimbursed for all travel costs in accordance with FAR 31.205 - 46, Travel Costs and GSA Per Diem Rates (www.gsa.gov/perdiem).

3. Requests for foreign travel must be submitted at least four weeks in advance and shall contain the following:

(i) meeting(s) and place(s) to be visited, with costs and dates;
(ii) names(s) and title(s) of Contractor personnel to travel and their functions in the contract project;
(iii) contract purpose to be served by the travel;
(iv) how travel of Contractor personnel will benefit and contribute to accomplishing the contract project, or will otherwise justify the expenditure of CMA contract funds;
(v) how such advantages justify the costs for travel and absence from the project of more than one person if such are suggested; and
(vi) what additional functions may be performed by the travelers to accomplish other purpose of the contact and thus further benefit the project.

ARTICLE B.5. ADVANCE UNDERSTANDINGS

a. **Subcontracts**

Prior written consent from the Contracting Officer in the form of a Contracting Officer Authorization (COA) is required for any subcontract that:

1. Is of the cost-reimbursement type or Time-and-Materials (T&M) for any amount;
2. Is Fixed-Price and exceeds $150,000 or 5% of the total estimated cost of the Contract.

The Contracting Officer shall request appropriate supporting documentation in order to review and determine authorization, pursuant with FAR Clause 52.244-2, Subcontracts (Alternate I). After receiving written consent of the subcontract by the Contracting Officer, a copy of the signed, executed subcontract and consulting agreement shall be provided to the Contracting Officer within ten (10) calendar days.

Note: Consulting services are treated as subcontracts and subject to the 'consent to subcontract' provisions set forth in this Article.

b. **Security**

A Security Plan is required for this effort. A security waiver may be requested. In the event a security waiver cannot successfully be attained, the Government will notify the Contractor who will subsequently be required to deliver a security plan to the Government, conforming with the following paragraphs.

The work to be performed under this contract will involve access to sensitive Biomedical Advanced Research and Development Authority [BARDA] program information. Upon contract award, the Program Protection Officer (PPO) will request submission of and review the Draft Security Plan in detail and submit comments within ten (10) business days to the CO to be forwarded to the Contractor. The Contractor shall review the Draft Security Plan comments, and if changes are required, submit a Final Security Plan to the U.S. Government within thirty (30) calendar days after receipt of the Program Protection Officer's (PPO) comments. The Final Security Plan shall include a timeline for compliance of all the required security measures. Upon completion of initiating all security measures, the Contractor shall supply to the CO and Contracting Officer's Representative (COR) a letter certifying compliance to the elements outlined in the Final Security Plan. The execution of the work under this contract shall be in accordance with the approved Final Security Plan. As outlined above, the content of the Final Security Plan shall be considered as part of the Contractor's Technical Proposal. The Contractor shall ensure that the storage, generation, transmission or exchanging of BARDA sensitive information has the appropriate security controls in place. At a minimum, the Final Security Plan shall address the following items:

Personnel Security Policies and Procedures including, but not limited to: Recruitment of new employees; Interview process; Personnel background checks; Suitability/adjudication policy; Access determination; Rules of behavior/conduct; Termination procedures; Non-disclosure agreements.

Physical Security Policies and Procedures including but not limited to: Internal/external access control; Identification/badge requirements; Facility visitor access; Parking areas and access; Barriers/perimeter fencing; Shipping, receiving and transport (on and off- site); Security lighting; Restricted areas; Signage; Intrusion detection systems; Closed circuit television; Other control measures.

Information Security Policies and Procedures including but not limited to: Identification of sensitive information; Access control/determination; Secured storage infrastructure; Document control; Retention/destruction requirements.

Information Technology Security Policies and Procedures including but not limited to: Intrusion detection and prevention systems;

firewalls, Encryption systems; Identification of sensitive information/media; Passwords; Removable media; Laptop policy; Media access control/determination; Secure storage; System document control; System backup; System disaster recovery.

Security Reporting Requirement - Violations of established security protocols shall be reported to the CO and COR within 24 hours of the contractor's discovery of any compromise, intrusion, loss or interference of its security processes and procedures. The Contractor shall ensure that all software components that are not required for the operation and maintenance of the database/control system have been removed and/or disabled. The Contractor shall provide to the CO and the COR information appropriate to Information and Information Technology software and service updates and/or workarounds to mitigate all vulnerabilities associated with the data and shall maintain the required level of system security.

* Certain confidential information contained in this document, marked [***], is filed separately with the Securities and Exchange Commission.

The Contractor will investigate violations to determine the cause, extent, loss or compromise of sensitive program information, and corrective actions taken to prevent future violations. The CO in coordination with BARDA will determine the severity of the violation. Any contractual actions resulting from the violation will be determined by the Contracting Officer.

c. **Confidential Treatment of Sensitive Information**

The Contractor shall, to the extent permitted by law, guarantee strict confidentiality of sensitive/confidential information/data that is provided by the USG during the performance of the contract. The USG has determined that certain information/data that the Contractor will be provided during the performance of the contract is of a sensitive nature.

Disclosure of confidential/sensitive 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.

Notwithstanding the foregoing, such information/data shall not be deemed of a sensitive or confidential nature with respect to the Contractor for purposes of this contract if such information/data: (a) was already known to the Contractor other than by prior disclosure by the USG or discovered through work under a prior USG contract; (b) was generally available or known, or was otherwise part of the public domain, at the time of its disclosure to the Contractor;
(c) became generally available or known, or otherwise became part of the public domain, after its disclosure to, or, with respect to the information/data by, the Contractor through no fault of the Contractor; (d) was disclosed to the Contractor, other than under an obligation of confidentiality or non-use, by a third party who had no obligation to the USG that controls such information/data not to disclose such information/data to others; or (e) was independently discovered or developed by the Contractor, as evidenced by its written records, without the use of information/data belonging to the USG.

The Contractor may disclose information/data of a sensitive nature provided by the USG to the extent that such disclosure is: (a) made in response to a valid order of a court of competent jurisdiction (b) otherwise required by law or regulation, (c) made by the Contractor to the Regulatory Authorities as required in connection with any filing, application or request for Regulatory Approval; provided, however, that reasonable measures shall be taken to assure confidential treatment of such information/data.

d. **Sharing of contract deliverables within United States Government (USG)**

In an effort to build a robust medical countermeasure pipeline through increased collaboration, BARDA may share technical deliverables with USG entities responsible for Medical Countermeasure Development. In accordance with recommendations from the Public Health Emergency Medical Countermeasure Enterprise Review, agreements established in the Integrated Portfolio Advisory Committee (PAC) Charter, and agreements between BARDA and the Department of Defense and the National Institutes of Health, BARDA may share technical deliverables and data created in the performance of this contract with colleagues within the Integrated Portfolio. This advance understanding does not authorize BARDA to share financial information outside of the United States Government. The Contractor is advised to review the terms of FAR 52.227-14, Rights in Data – General, regarding the government's rights to deliverables submitted during performance as well as the government's rights to data contained within those deliverables.

* Certain confidential information contained in this document, marked [***], is filed separately with the Securities and Exchange Commission.

e. **Approval of Protocols**

The Contractor shall submit all protocols as referenced under this Contract to the COR f o r review and approval. The Government requires no fewer than eight (8) business days to perform a review. The Contractor shall take this review time into account and submit protocols as early as possible to avoid delays. The Government's comments and feedback shall be addressed prior to approval.
The COR will review and provide approval of protocols.

f. **Rights in Data**

The contract will incorporate Alternate II to FAR Clause 52.227-14, Rights in Data—general, pursuant to FAR Clause 52.227-14 (g)(3). In the event that the U.S. Government requires the delivery of pre-existing privately funded data, Opiant Pharmaceuticals, Inc. will identify that specific pre-existing privately funded data and that data will be marked with the limited rights notice specified under FAR Clause 52.227-14 (g)(3)(a).

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. STATEMENT OF WORK

Independently and not as an agent of the government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities not otherwise provided by the government as needed to perform the Statement of Work dated September 19, 2018, set forth in SECTION J - List of Attachments, attached hereto and made a part of the contract.

ARTICLE C.2. REPORTING REQUIREMENTS

Refer to ARTICLE F.2 for specific instructions regarding Reporting Requirements.

ARTICLE C.3. CONTRACT MANAGEMENT REPORT REQUIREMENTS

The Contractor and BARDA agree that contract management requirements contained in the contract are limited to the implementation requirements outlined in Gantt Chart in the Attachments (Section J.) of the contract. The total amount of this contract reflects the use of the proposed budget dated September 19, 2018.

ARTICLE C.4. PROJECT MEETING CONFERENCE CALLS

A conference call between the Contracting Officer's Representative and designees and the Contractor's Project Leader/delegate and designees shall occur bi-weekly or as otherwise mutually agreed upon by the USG and the Contractor or determined by the Contracting Officer. During this call the Contractor's Project Leader/delegate and designees will discuss the activities since the last call, any problems that have arisen and the activities planned until the next call takes place. The Contractor's Project Leader/delegate may choose to include other key personnel on the conference call to give detailed updates on specific projects or this may be requested by the Contracting Officer's Representative. Electronic copy of conference call meeting minutes/summaries shall be provided via e-mail to the CO, COR, and uploaded in e-room by the Contractor within five (5) business days after the conference call is held.

ARTICLE C.5. OTHER PROJECT MEETINGS

a. **Kickoff Meeting**

The Contractor and USG shall conduct a kickoff meeting within 30 calendar days after contract award. Contractor shall provide an itinerary/agenda no later than 5 business days before meeting. Minutes from the kickoff meeting must be provided within 10 business days of the event.

b. **Quarterly and Ad-Hoc Meetings**

The contractor shall participate in Project Meetings to coordinate the performance of the contract, as requested by the Contracting Officer's Representative. These meetings may include face-to-face meetings with CMA and BARDA in Washington, D.C. and at work sites of the Contractor and subcontractors. Such meetings may include, but are not limited to, meetings of the Contractor to discuss study designs, site visits to the Contractor's facilities, and meetings with the Contractor and HHS officials to discuss the technical, regulatory, and ethical aspects of the program, and, subject to the data rights, outside experts and USG personnel as required by the Contracting Officer's Representative in order to facilitate review of contract activities. Contractor shall provide itinerary/agenda at least five business days in advance of face-to-face meeting.

c. **Face-to-Face Project Review Meetings**

The contractor shall, at a time to be determined later, present a comprehensive review of contract progress to date in a face-to-face meeting in Washington, DC. The contractor will be responsible for updating BARDA program on technical progress under the Statement of Work.
Presentation must be delivered seven (7) business days prior to the scheduled meeting.

* Certain confidential information contained in this document, marked [***], is filed separately with the Securities and Exchange Commission.

SECTION D – PACKAGING, MARKING AND SHIPPING

All deliverables required under this contract shall be packaged, marked and shipped in accordance with USG 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.

Unless otherwise specified by the Contracting Officer, delivery of reports to be furnished to the USG under this contract (including invoices) shall be delivered to CMA and BARDA electronically along with a concurrent email notification to the Contracting Officer, Contract Specialist, and COR (as defined in SECTION F.3.
ELECTRONIC SUBMISSION) summarizing the electronic delivery.

SECTION E – INSPECTION AND ACCEPTANCE

ARTICLE E.1. FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)

This contract incorporates the following clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a

* Certain confidential information contained in this document, marked [***], is filed separately with the Securities and Exchange Commission.

clause may be accessed electronically at these addresses: https://www.acquisition.gov/FAR/ . HHSAR Clauses at: http://www.hhs.gov/policies/hhsar/subpart352.html.

FAR Clause	Title and Date
52.246-9	Inspection of Research and Development (Short Form) (Apr 1984)

ARTICLE E.2. DESIGNATION OF GOVERNMENT PERSONNEL

For the purpose of this SECTION E, the designated Contracting Officer's Representative (COR) is the authorized representative of the Contracting Officer. The COR will assist in resolving technical issues that arise during performance. The COR however is not authorized to change any contract terms or authorize any changes in the Statement of Work or modify or extend the period of performance, or authorize reimbursement of any costs incurred during performance.

ARTICLE E.3. INSPECTION, ACCEPTANCE AND CONTRACT MONITORING

Inspection and acceptance of the materials materials/services and documentation called for herein shall be accomplished by the Contracting Officer or a duly authorized representative.

Inspection and acceptance will be performed at:

Contracts Management and Acquisition (CMA)
Office of the Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services
330 Independence Avenue, S.W., Room G640 Washington, D.C. 20201

a. **Site Visits and Inspections**

At the discretion of the USG and independent of activities conducted by the Contractor, with 48 hours' notice to the contractor, the USG reserves the right to conduct site visits and inspections on an as needed basis, including collection of product samples and intermediates held at the location of the contractor, or subcontractor. All costs reasonably incurred by the Contractor and subcontractor for such visit and/or inspection shall be allowable costs subject to the Allowable cost requirements in FAR Subpart 31.2. The Contractor shall coordinate these visits and shall have the opportunity to accompany the USG on any such visits. Under time-sensitive or critical situations, the USG reserves the right to suspend the 48 hour notice to the Contractor. The areas included under the site visit could include, but are not limited to: security, regulatory and quality systems, manufacturing processes and cGMP/ GLP/GCP compliance.

If the USG, Contractor, or other party identifies any issues during an audit, the Contractor shall capture the issues, identify potential solutions, and provide a report to the USG for review and acceptance.

- If issues are identified during the audit, the Contractor shall submit a report to the CO and COR within five (5) business days detailing the finding and corrective action(s) of the audit.
- COR and CO will review the report and provide a response to the Contractor within ten (10) business days.
- Once corrective action is completed, the Contractor will provide a final report to the CO and COR.

SECTION F – DELIVERIES OR PERFORMANCE

ARTICLE F.1. PERIOD OF PERFORMANCE

Base Period

Under CLIN 0001, the estimated period of performance for the base performance segment of this contract shall be from September 19, 2018 through September 30, 2019 (12 months and 11 days).

Option CLINS

CLIN	Option	Est. Period of Performance	Supplies/ Services
2	1	[***]	CMC Batch Manufacturing
3	2	[***]	Regulatory NDA

NOTE: Base period and all option periods (if exercised in accordance with FAR clause FAR clause 52.217-09, Option to Extend the Term of the Contract (Mar 2000), shall not exceed [***].

ARTICLE F.2. DELIVERABLES

Successful performance of the final contract shall be deemed to occur upon completion of performance of the work set forth in the Statement of Work dated September 19, 2018, set forth in SECTION J - List of Attachments of this contract and upon delivery and acceptance by the Contracting Officer, as required by the Statement of Work, of each of the deliverables described in SECTION C, SECTION F, and SECTION J, Attachment 2, “Milestones and Deliverables Chart”.

All deliverables and reporting documents listed within this section shall be delivered electronically (as defined in SECTION F.3. ELECTRONIC SUBMISSION) to the Contracting Officer (CO), Contract Specialist (CS), the Contracting Officer’s Representative (COR) and the Alternate COR unless otherwise specified by the Contracting Officer.

a. **Summary of Contract Deliverables**

Unless otherwise specified by the Contracting Officer, the deliverables identified in this SECTION F shall also be delivered electronically to the designated eRoom along with a concurrent email notification sent to the CO, the CS, the COR and the Alternate COR stating delivery has been made.

All paper/hardcopy documents/reports submitted under this contract shall be printed or copied, double- sided, on at least 30 percent post-consumer fiber paper, whenever practicable, in accordance with FAR 4.302(b). Hard copies of deliverables and reports furnished to the USG under the resultant Contract (including invoices) shall be addressed as follows:

HHS/ASPR/CMA
ATTN: Juan Wooten, Contracting Officer
330 Independence Avenue, S.W., Room G640
Washington, DC 20201
Email: juan.wooten@hhs.gov

HHS/ASPR/BARDA

* Certain confidential information contained in this document, marked [***], is filed separately with the Securities and Exchange Commission.

ATTN: Kristen Herring, Contracting Officer's Representative 330 Independence Avenue, S.W., Room G644

Washington, DC 20201
Email: kristen.herring@hhs.gov

Technical Reports			
Item	**Deliverable**	**Description**	**Deliverable Schedule**
1	Bi- weekly Teleconference and Meeting Minutes	The Contractor shall prepare minutes of all "Project Meetings and "Project Meeting Conference Calls" as defined in Article C. of this contract. In preparation for the monthly calls, briefing materials, including the agenda and documents and information to be discussed will be prepared as needed.	Contractor shall provide teleconference agenda and related materials twenty-four (24) hours in advance of the call. Contractor provides meeting minutes to COR within five (5) business days of the meeting. COR reviews, comments, and approves minutes within 15 business days of receipt.
2	Monthly Technical Progress Report and Invoice	Monthly Progress report shall address the progress occurring over the corresponding period of time. See below, ARTICLE F.2.(b), "Detailed Description of Select Contract Deliverables," for detailed instructions. Additionally, submission of the Monthly Technical Progress Report will contain the invoice for actual costs incurred during the previous month that work was performed under the contract. The costs incurred in the invoice will be justified in a summary report contained within the Monthly Technical Progress Report.	The 15th calendar day of each month following the first full month of the contract award. The Monthly Progress Report will not be required in months when an Annual or Final Technical Progress Report is due.
3	Annual Progress Report	Annual Progress report shall address the progress occurring over the corresponding period of time. See below, Article F.2.(b), "Detailed Description of Select Contract Deliverables," for detailed instruction.	The 15th calendar day of the month following the end of each 12- month performance period. The Monthly Progress Report will not be required in months when an Annual Progress report is due
4	In-Process Review (GO/NO GO Decision Gate) Presentation	In preparation for the IPR, the Contractor shall prepare a presentation demonstrating the technical progress made towards completion of the tasks under each work segment. The presentation shall demonstrate the status or completion of the milestones and deliverables as specified under Section F.	The presentation must be submitted to the CO/COR thirty (30) business days prior to the IPR IPR for BARDA review and comment. Subsequently, a revised/final presentation will be required ten (10) business days prior to the IPR. The CO will provide a written response within ten (10) business days on the decision to exercise or not exercise an option.
5	Contract Management Report	As described in Article C.3.	The 15th calendar day of each month following the first full month of the contract award.
6	Draft Final Technical Progress Report	A draft Final Report containing a summation of the work performed under each task and subtask and the results obtained for the entire contract Period of Performance (PoP). The draft report shall be duly marked as "Draft." BARDA will provide comments that the Contractor shall incorporate into the Final Technical Progress Report.	Forty-five (45) calendar days before the completion date of the contract.
7	Final Technical Progress Report	A Final Report containing a summation of the work performed and the results obtained for the entire contract Period of Performance (PoP).	Thirty (30) calendar days after the technical period of performance.

8	Summary of Salient Results	Contractor shall submit, with the Final Report, a summary (not to exceed 200 words) of salient results achieved during the performance of the contract.	On or before the expiration date of the contract.
9	Deviation Notification. Changes to Execution of Planned Tasks and Mitigation Strategy	In order to process for changing tasks, including activities associated with task content, cost and schedule per IMP/Gantt baseline, the Contractor shall notify the Government of significant changes, justification, and rationale for proposed alternative in writing. Cost reallocation and reconciliation of the budget should be included. Contractor shall provide a high-level management strategy for risk mitigation and update the Risk Management Plan	Notice due within 1 week after discovery or need for changes to product development plan per Gantt identified. Contractor shall revise the IMP/Gantt within thirty (30) calendar days, update monthly s part of the Monthly Progress Report, and update the Risk Management Plan. Contractor must address, in writing, all concerns raised by BARDA and re-submit a IMP/GANTT that reflects or addresses BARDA's concerns.
10	Development Report	Final Reports detailing the parameters and capacity of upstream and downstream conditions.	Upon successful completion.

Other Technical Reports		
Item		**Deliverable Schedule**
11		Within fifteen (15) calendar days of the audit
12		Within five (5) business days of each meeting for Contractor's minutes and upon receipt of minutes from FDA/regulatory agency.

13	FDA/Regulatory Agency Submissions	BARDA shall provide comment within five (5) business days after receipt. BARDA reserves the right to request more than 5 business days for review of any regulatory submission that is of significant length. The Contractor shall inform BARDA of the anticipated submission length so BARDA can make a determination if more than 5 business days will be needed to complete its review of the document.
14	Supplemental Technical Documents	Upon request. Contractor shall provide CO and COR with deliverables from the following contract funded activities: Process Development Reports; Stability Assay Reports; Assay Qualification Plan/Report; Assay Validation Plan/Report; Assay Technology Transfer Report; Batch Records; pertinent Contractor/ Subcontractor Standard Operating Procedures (SOPs); Master Production Records; Certificate of Analysis; Clinical Studies Data or Reports. The CO and COR reserve the right to request within the PoP a nonproprietary technical document for distribution within the USG. Contractor shall provide technical document within 5 business days of CO or COR request. Contractor can request additional time on an as-needed basis. *If corrective action is recommended, the Contractor must address, in writing, concerns raised by BARDA.
15	Invention Report Annual Utilization Report	Due on or before the 30th of the month following each 12-month period of performance.
16	Final Invention Report	Due on or before the completion date of the contract.
17	Kickoff Meeting	Within thirty (30) calendar days of contract award.

b. **Detailed Description of Select Contract Deliverables**

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 Contractor shall submit a Monthly Progress Report on or before the 15th calendar day following the last day of each reporting period and shall include the following:

A cover page that includes the contract number and title; the type of report and period that it covers; the Contractor's name, address, telephone number, fax number, and e-mail address; and the date of submission;

SECTION I - An introduction covering the purpose and scope of the contract effort; SECTION II – PROGRESS

SECTION II Part A: OVERALL PROGRESS - A description of overall progress;

SECTION II Part B: MANAGEMENT AND ADMINISTRATIVE UPDATE - A
description of all meetings, conference calls, etc. that have taken place during the reporting period. Include progress on administration and management issues (e.g. evaluating and managing subcontractor performance and personnel changes);

SECTION II Part C: TECHNICAL PROGRESS - For each activity related to the Gantt chart, document the results of work completed and costs incurred during the period covered in relation to proposed progress, effort and budget. The report shall be in sufficient detail to explain comprehensively the results achieved. The description shall include pertinent data and/or graphs in sufficient detail to explain any significant results achieved and preliminary conclusions resulting from analysis and scientific evaluation of data accumulated to date under the contract. Include progress or status updates for all SOW tasks in each of the monthly technical progress reports for which there is activity ongoing in that SOW task area(s) as well as data for completed studies in any SOW task. The report shall also include a description of problems encountered and proposed corrective action; differences between planned and actual progress, why the differences have occurred and what corrective actions are planned; preliminary conclusions resulting from analysis and scientific evaluation of data accumulated to date under the project.

SECTION II Part D: PROPOSED WORK - A summary of work proposed for the next reporting period and preprints/reprints of papers and abstracts, and a current/updated Gantt chart.

SECTION II Part E: Outstanding Issues/Anticipated Areas of Concern - a list of any existing contractual concerns that impact the technical scope of work, schedule, or cost, as well as a list of potential or anticipated areas of concern that may be encountered in the future months.

A Monthly Progress Report will not be required in the same month that the Annual or Final Technical Progress Reports are submitted.

2. **Annual Progress Reporting Requirement**

This report shall include a summation 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 year of performance plus any fractional part of the initial year. Thereafter, the reporting period shall consist of each calendar year.

The Contractor shall submit an Annual Progress Report on or before the 15th calendar day following the last day of each reporting period and shall include the following:

A cover page that includes the contract number and title; the type of report and period that it covers; the Contractor's name, address, telephone number, fax number, and e-mail address; and the date of submission;

SECTION I-EXECUTIVE SUMMARY - A brief overview of the work completed and major accomplishments achieved during the reporting period.

SECTION II-PROGRESS

SECTION II Part A: OVERALL PROGRESS - A description of overall progress highlighting the significant accomplishments in

the past year;

SECTION II Part B: MANAGEMENT AND ADMINISTRATIVE UPDATE - A
description of all meetings, conference calls, etc. that have taken place during
the reporting period. Include progress on administration and management issues (e.g. evaluating and managing subcontractor performance and personnel changes);
SECTION II Part C: TECHNICAL PROGRESS - For each activity, document the results of work completed and cost incurred during the period covered in relation to proposed progress, effort and budget. The report shall be in sufficient detail to explain comprehensively the results achieved. The description shall include pertinent data and/or graphs in sufficient detail to explain any significant results achieved and preliminary conclusions resulting from analysis and scientific evaluation of data accumulated to date under the contract. The report shall include a description of problems encountered and proposed corrective action; differences between planned and actual progress, why the differences have occurred and what corrective actions are planned; preliminary conclusions resulting from analysis and scientific evaluation of data accumulated to date under the project. The report should summarize progress made under each SOW task.

SECTION II Part D: PROPOSED WORK - A summary of work proposed for the next reporting period; and preprints/reprints of papers, abstracts and a current Gantt chart.

A Monthly and Annual Progress Report will not be required for the period when the Final Technical Progress Report is due and a Monthly Progress Report will not be required in the same month that the Annual Progress Report is submitted.

Draft Final Technical Progress Report and Final Technical Progress Report

These reports are to include a summation of the work performed and results obtained for the entire contract period of performance, detailing accomplishments for each task. This report shall be in sufficient detail to describe comprehensively the results achieved. The Draft Final Report and Final Report shall be submitted in accordance with the DELIVERIES Article in

SECTION F of the contract. The Draft Final Technical Progress Report shall be submitted forty-five (45) calendar days before completion date of the contract and the Final Technical Progress Report shall be submitted 30 Calendar days post technical period of performance. The report shall conform to the following format:

Cover page to include the contract number, contract title, performance period covered, Contractor's name and address, telephone number, fax number, e- mail address and submission date;

SECTION I: EXECUTIVE SUMMARY - Summarize the purpose and scope of the contract effort including a summary of the major accomplishments relative to the specific activities set forth in the Statement of Work.;

SECTION II: RESULTS - A detailed description of the work performed related to the Gantt chart, the results obtained, and the impact of the results on the scientific and/or public health community, including a listing of all manuscripts (published and in preparation) and abstracts presented during the entire period of performance, and a summary of all inventions.

Draft Final Technical Progress Report: The Contractor is required to submit the Draft Final Technical Progress Report to the Contracting Officer's Representative and Contracting Officer. This report is due forty-five (45) calendar days before the completion date of the contract. The Contracting Officer's Representative and Contracting Officer will review the

Draft Final Technical Progress Report and provide the Contractor with comments within fifteen (15) calendar days after receipt.

Final Technical Progress Report: The contractor shall incorporate all BARDA comments into the Final Technical Progress Report. The Contractor will deliver the final version of the Final Technical Progress Report 30 Calendar days post technical period of performance.

3. **Summary of Salient Results**

On or before the expiration of the contract the Contractor shall submit, with the Final Technical Progress Report, a summary (not to exceed 200 words) of salient results achieved during the performance of the contract.

4. **Audit Reports**

Within fifteen (15) calendar days of an audit related to conformance to FDA regulations and guidance, including adherence to GLP, GMP, GCP guidelines, the Contractor shall provide copies of the audit report (so long as received from the FDA) and a plan for addressing areas of nonconformance to FDA regulations and guidelines for GLP, GMP, or GCP guidelines as identified in the final audit report.

5. **Copies of FDA/Regulatory Agency Correspondence and Meeting Summaries**

- Within five business days of any formal meeting with the FDA or other regulatory agency, the contractor shall forward the initial draft minutes to BARDA. The contractor shall forward final draft minutes when available.
- Within five business days of any informal meeting with the FDA or other regulatory agency, the contractor shall forward the final draft minutes to BARDA.
- The contractor shall forward the dates and times of any meeting with the FDA and other regulatory agencies to BARDA and make arrangements for appropriate BARDA staff to attend the meetings.
- The contractor shall provide BARDA the opportunity to review and comment upon any documents to be submitted to the FDA or other regulatory agency. The contractor shall provide BARDA with five (5) business days in which to review and provide comments back to the contractor prior to the contractor's submission to the FDA.
- The contractor shall forward pertinent contractor Standard Operating Procedures (SOPs) upon request from Project Officer/Contracting Officer.
- The contractor shall provide upon request animal study and/or other technology packages developed under this contract. Packages shall include complete protocols and critical reagents for animal models developed and/or improved with contract funding.
- The contractor shall provide upon request raw data and/or specific analysis of data generated with USG funds.

6. **Other Reports/Deliverables**

- **Government Rights in Data and Inventions**
- **Institutional Biosafety Approval**

* Certain confidential information contained in this document, marked [***], is filed separately with the Securities and Exchange Commission.

The Contractor shall provide documentation of materials submitted for Institutional Biosafety Committee Review and documentation of approval of experiments at the request of the Contracting Officer's Representative.

- **Experimental Protocols**

The Contractor shall submit all study/experiment/test plans, designs, and protocols.

7. **Data**

The Contractor shall provide data and/or specific analysis of data generated with contract funding at the request of the Contracting Officer's Representative.

Contract Management Report (CMR) Deliverables

i. **Contract Management Report (CMR)**

Contractor will provide a monthly CMR at an agreed upon reporting level using WBS, Gantt Chart and budgetary Variance Analysis report formats agreed upon by the Contracting Officer.

- Contractor shall provide CMR as part of the Monthly Progress Report (this requirement begins only as set forth in the Contract Milestones & Related Deliverables table)
- Contractor shall provide top level or key changes in baseline cost as a result of anticipated cost savings or risks
- In accordance with FAR 52.215-2, Audit and Records-Negotiation (Oct 2010), the USG may request, on a monthly or ad hoc basis that the Contractor provide raw data at a reporting level or lower level as ASPR deems necessary.
- Contractor must address, in writing, all concerns raised by the USG.
- Reporting will commence after the CMR system has been implemented but no later than six (6) months after start of base period.

ii. **Integrated Master Plan (IMP)**

The Contractor shall provide an IMP including WBS, critical path milestones, and Earned Value Management Plan

- Contractor shall provide the draft IMP within 180 days of contract award with final due 8 months after award and updated monthly as part of the Monthly Progress Report
- Contractor must address, in writing, all concerns raised by the USG.

iii. **Performance Measurement Baseline Review (PMBR)**

PMBR Report shall address each of the items listed below and be cross- referenced to the IMP, WBS, SOW, and Risk Management Plan.

- Contractor provides baseline proposal
- Responsibility Assignment Matrix
- A description of the work scope through control account Work Authorization Documents and/or WBS Dictionary down to the agreed upon control account level.
- Template for work packages
- Integrated Master Schedule (IMS) with the inclusion of agreed major milestones and control account plans for all control accounts
- Baseline revision documentation and program log(s) risk management plan
- PMBR is due within one year of contract award
- Contractor shall provide baseline proposal .ppt briefing 10 business days prior to meeting
- Contractor provides agenda to COR 2 business days in advance of meeting
- COR approves (with CO concurrence) and distributes agenda
- COR approves (with CO concurrence) all meeting material
- Contactor provides minutes with 2 business days of the meeting
- COR reviews and approves (with CO concurrence) minutes

- ASPR will review documentation and provide written comments and questions to Contractor
- Contractor shall address BARDA's comments and resubmit PMBR report for BARDA approval within 10 business days.

iv. **Risk Management Plan**

The Contractor shall provide a Risk Management Plan that outlines the impacts of each risk in relation to the cost, schedule, and performance objectives. The plan shall include risk mitigation strategies. Each risk mitigation strategy will capture how the corrective action will reduce impacts on cost, schedule and performance.

- Due within 180 days of contract award
- Contractor provides updated Risk Management Plan in Monthly Progress Report

- ASPR shall provide Contractor with a written list of concerns in response plan submitted
- Contractor must address, in writing, all concerns raised by ASPR within 20 business days of Contractor's receipt of ASPR's concerns.

v. **Requirement for Notification of Deviation and Mitigation Strategy**

Process for changing IMS activities associated with cost and schedule as baselined at the PMBR. Contractor shall notify ASPR of significant changes to the IMS defined as increases in cost above 10% for Go/No Go Milestones or schedule slippage of more than 180 days, which would require an extension to the period of performance. Contractor shall provide a high level management strategy for risk mitigation. Notice due within one (1) business days after discovery.

ARTICLE F.3. ELECTRONIC SUBMISSION

For electronic delivery, the Contractor shall upload documents to the appropriate folder on https://eroom.bardatools.hhs.gov/eRoom ("eRoom") which is the designated USG file sharing system. The USG shall provide two contractor representatives authorized log in access to the file share program. Each representative must complete a mandatory training provided by the USG prior to gaining user access. A notification email should be sent to the CO and COR upon electronic delivery of any documents.

* Certain confidential information contained in this document, marked [***], is filed separately with the Securities and Exchange Commission.

ARTICLE F.4. SUBJECT 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, one copy of an annual utilization report, and a copy of the final invention statement, shall be submitted to the Contracting Officer. A final invention statement (see FAR 27.303 (b)(2)(ii)) shall be submitted to the Contracting Officer on the expiration date of the contract.

Reports and documentation submitted to the Contracting Officer shall be sent to the address set forth in SECTION G – CONTRACT ADMINISTRATION DATA.

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.

SECTION G - CONTRACT ADMINISTRATION DATA

ARTICLE G.1. CONTRACTING OFFICER

The following Contracting Officer (CO) will represent the USG for the purpose of this contract:

Juan Wooten

Contracting Officer DHHS/OS/ASPR/CMA
330 Independence Avenue, S.W. Room G644
Washington, D.C. 20201
(202) 692-4624
Juan.wooten@hhs.gov

1) The Contracting Officer (CO) is the only individual who can legally commit the USG to the expenditure of public funds. No person other than the Contracting Officer can make any changes to the terms, conditions, general provisions, or other stipulations of this contract.

2) The Contracting Officer is the only person with the authority to act as agent of the USG 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 of any costs incurred during the performance of this contract; (5) otherwise change any terms and conditions of this contract.

3) No information other than that which may be contained in an authorized modification to this contract, duly issued by the Contracting Officer, which may be received from any person employed by the US government, other otherwise, shall be considered grounds for deviation from any stipulation of this contract.

4) The USG may unilaterally change the CO or CS designation

ARTICLE G.2. CONTRACTING OFFICER'S REPRESENTATIVE (COR) and ALTERNATE CONTRACTING OFFICER'S REPRESENTATIVE (COR)

The following COR and Alternate COR will represent the government for the purpose of this contract:

COR:

Kristen Herring
Biomedical Advanced Research and Development Authority (BARDA) Office of the Assistant Secretary for Preparedness and Response Department of Health and Human Services
Email: Kristen.herring@hhs.gov (202) 260-1388

Alternate COR:

Judith Laney

Biomedical Advanced Research and Development Authority (BARDA) Office of the Assistant Secretary for Preparedness and Response Department of Health and Human Services
judith.laney@hhs.gov

* Certain confidential information contained in this document, marked [***], is filed separately with the Securities and Exchange Commission.

(202) 205-8043

Mailing Address:

330 Independence Avenue, SW G644 Washington, D.C. 20201 The COR and Alternate are responsible for:

1) Recommending to the Contracting Officer changes in requirements;
2) Assisting the Contracting Officer in 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 USG may unilaterally change the COR designation.

ARTICLE G.3. KEY PERSONNEL

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 USG 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 USG may modify the contract to add or delete key personnel at the request of the Contractor or USG.

The following individuals are considered to be essential to the work being performed hereunder:

Name	Title
David O'Toole	Chief Financial Officer
Carina Caulfield	Director of Program Management

* Certain confidential information contained in this document, marked [***], is filed separately with the Securities and Exchange Commission.

ARTICLE G.4. INVOICE/FINANCING REQUEST AND CONTRACT FINANCIAL REPORTING

Include Program Support Center (PSC) in Receipt of Invoices:

Documents shall be delivered electronically to the Contracting Officer (CO), the Contracting Specialist (CS), the Contracting Officer's Representative (COR) and PSC. Unless otherwise specified by the Contracting Officer all deliverables and reports furnished to the Government under the resultant contract (including invoices) shall be addressed as follows:

Juan Wooten Contracting Officer HHS/ASPR/CMA 330 Independence Ave., S.W., Room G640 Washington, DC 20201 Email:juan.wooten@hhs.gov	Kristen Herring Contracting Officer Representative HHS/ASPR/BARDA 330 Independence Ave., S.W., Room G640 Washington, DC 20201 Email: kristen.herring@hhs.gov	PSC_Invoices@psc.hhs.gov

a. Contractor invoices/financial reports shall conform to the form, format, and content requirements of the instructions for Invoice/Financing requests and Contract Financial Reporting.

b. Monthly invoices must include the cumulative total expenses to date, adjusted (as applicable) to show any amounts suspended by the USG.

c. The Contractor agrees to immediately notify the CO in writing if there is an anticipated overrun (any amount) or unexpended balance (greater than 10 percent) of the estimated costs for the base period or any option period(s) (See estimated costs under Articles B.2) and the reasons for the variance. These requirements are in addition to the specified requirements of FAR Clause 52.232-20, Limitation of Cost that is incorporated by reference under Article I.1 which states;

Limitation of Cost (Apr 1984)

(a) The parties estimate that performance of this contract, exclusive of any fee, will not cost the Government more than (1) the estimated cost specified in the Schedule or, (2) if this is a cost-sharing contract, the Government's share of the estimated cost specified in the Schedule. The Contractor agrees to use its best efforts to perform the work specified in the Schedule and all obligations under this contract within the estimated cost, which, if this is a cost-sharing contract, includes both the Government's and the Contractor's share of the cost.

(b) The Contractor shall notify the Contracting Officer in writing whenever it has reason to believe that—

(1) The costs the Contractor expects to incur under this contract in the next 60 days, when added to all costs previously incurred, will exceed 75 percent of the estimated cost specified in the Schedule; or

(2) The total cost for the performance of this contract, exclusive of any fee, will be either greater or substantially less than had been previously estimated.

(c) As part of the notification, the Contractor shall provide the Contracting Officer a revised estimate of the total cost of performing this contract.

(d) Except as required by other provisions of this contract, specifically citing and stated to be an exception to this clause—

(1) The Government is not obligated to reimburse the Contractor for costs incurred in excess of (i) the estimated cost specified in the Schedule or, (ii) if this is a cost-sharing contract, the estimated cost to the Government specified in the Schedule; and
(2) The Contractor is not obligated to continue performance under this contract (including actions under the Termination clause of this contract) or otherwise incur costs in excess of the estimated cost specified in the Schedule, until the Contracting Officer (i) notifies the Contractor in writing that the estimated cost has been increased and (ii) provides a revised estimated total cost of performing this contract. If this is a cost-sharing contract, the increase shall be allocated in accordance with the formula specified in the Schedule.

(e) No notice, communication, or representation in any form other than that specified in paragraph (d)(2) of this clause, or from any person other than the Contracting Officer, shall affect this contract's estimated cost to the Government. In the absence of the specified notice, the Government is not obligated to reimburse the Contractor for any costs in excess of the estimated cost or, if this is a cost-sharing contract, for any costs in excess of the estimated cost to the Government specified in the Schedule, whether those excess costs were incurred during the course of the contract or as a result of termination.

(f) If the estimated cost specified in the Schedule is increased, any costs the Contractor incurs before the increase that are in excess of the previously estimated cost shall be allowable to the same extent as if incurred afterward, unless the Contracting Officer issues a termination or other notice directing that the increase is solely to cover termination or other specified expenses.

(g) Change orders shall not be considered an authorization to exceed the estimated cost to the Government specified in the Schedule, unless they contain a statement increasing the estimated cost.

(h) If this contract is terminated or the estimated cost is not increased, the Government and the Contractor shall negotiate an equitable distribution of all property produced or purchased under the contract, based upon the share of costs incurred by each.

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

e. An electronic copy of the payment request shall be uploaded into the designated eRoom (as defined in SECTION F.3 ELECTRONIC SUBMISSION) and an e-mail notification of the upload will be provided to the CO and COR.

f. All invoice submissions shall be in accordance with FAR Clause 52.232-25, Prompt Payment (Jul 2013).

g. Invoices - Cost and Personnel Reporting, and Variances from the Negotiated Budget

The Contractor agrees to provide a detailed breakdown on invoices of the following cost categories:

* Certain confidential information contained in this document, marked [***], is filed separately with the Securities and Exchange Commission.

a. Direct Labor - List individuals by name, title/position, hourly/annual rate, level of effort (actual hours or percentage of effort), and amount claimed.
b. Fringe Benefits - Cite rate and amount
c. Overhead - Cite rate and amount
d. Materials & Supplies - Include detailed breakdown when total amount is over $1,000.
e. Travel - Identify travelers, dates, destination, purpose of trip, and total breaking out amounts for transportation (plane, car etc.), lodging, M&IE. Cite COA, if appropriate. List separately, domestic travel, general scientific meeting travel, and foreign travel.
f. Consultant Fees - Identify individuals, amounts and activities. Cite appropriate COA
g. Subcontracts - Attach subcontractor invoice(s). Cite appropriate COA
h. Equipment - Cite authorization and amount. Cite appropriate COA
i. Other Direct Costs - Include detailed breakdown when total amount is over $1,000.
j. G&A - Cite rate and amount.
k. Total Cost
l. Fee
m. Total Cost Plus Fixed Fee

Monthly invoices must include the cumulative total expenses to date, adjusted (as applicable) to show any amounts suspended by the USG. Nothing in this section discharges the contractor's responsibility to comply with any applicable FAR Parts 30 or 31 clauses' relating to cost reimbursement subcontracts. In order to verify allowability, further breakdown of costs may be requested at the USG's discretion. The Contractor shall subcontract with Firm Fixed Price Contracts to the maximum extent practicable.
Additional instructions and an invoice template are provided in Attachment 3, Invoice/Financing Request Instructions and Contract Financial Reporting Instructions for Cost-Reimbursement Type Contracts. All invoices must be signed by a representative of the contractor authorized to certify listed charges are accurate and comply with government regulations. Invoices should be submitted electronically (in accordance with ARTICLE F.4., (ELECTRONIC SUBMISSION) and in hard copy with original signature.

ARTICLE G.5. INDIRECT COST RATES

The following contractor established provisional billing rates are incorporated into the contract, and will be utilized for billing purposes during both the base and contract option periods pending the establishment of final indirect cost rates for each fiscal year or until revised by the contracting officer in accordance with the provisions of FAR 42.705-1. See FAR Clause 52.216-7.

Opiant Pharmaceuticals		
Rate Type	**Rate**	**Allocation Base**
Fringe Benefits	18.00%	Total salaries and wages
Overhead/G&A	0.0%	Total direct costs

Use of the above provisional rates does not change any cost ceilings, contract obligations, or specific allowance or disallowance provided for in the contract.

Contractor must notify the contracting officer promptly for an adjustment of the provisional rates if it becomes evident that the rates would cause substantial overpayment or underpayment of indirect expenses to Opiant Pharmaceuticals.

* Certain confidential information contained in this document, marked [***], is filed separately with the Securities and Exchange Commission.

The final billing rates for each fiscal year will be based on the incurred cost submission subject to Government audit determination. Indirect costs rate proposals must be submitted to the cognizant agency's Contracting Officer within 6 months subsequent to each of the contractor's fiscal year ends. (See also FAR Clause 52.216-7(d) (2) incorporated herein). Copies of the indirect cost submission for each fiscal year must also be submitted to the CMA contracting officer, and the CMA auditor identified as follows:

Director, Acquisition Program Support
Contacts Management and Acquisition (CMA)
Office of the Assistant Secretary for Preparedness and Response (ASPR) US Department of Health and Human Services (DHHS)
300 Independence Avenue, SW, Room G644 Washington, DC 20201

ARTICLE G.6. REIMBURSEMENT OF COST

1) The USG shall reimburse the Contractor those costs determined by the Contracting Officer to be allowable (hereinafter referred to as allowable cost) in accordance with FAR 52.216-7, Allowable Cost and Payment and FAR Subpart 31.2. Examples of allowable costs include, but are not limited to, the following:

   a) All direct materials and supplies that are used in the performing of the work provided for under the contract, including those purchased for subcontracts and purchase orders.

   b) All direct labor, including supervisory, that is properly chargeable directly to the contract, plus fringe benefits.

   c) All other items of cost budgeted for and accepted in the negotiation of this basic contract or modifications thereto.

   d) Travel costs including per diem or actual subsistence for personnel while in an actual travel status in direct performance of the work and services required under this contract subject to the restrictions under Article B.4. b. and the following:
      i. Air travel shall be by the most direct route using "air coach" or "air tourist" (less than first class) unless it is clearly unreasonable or impractical (e.g., not available for reasons other than avoidable delay in making reservations, would require circuitous routing or entail additional expense offsetting the savings on fare, or would not make necessary connections) and must comply with the Fly America Act (49 U.S.C. 40118).

      ii. Rail travel shall be by the most direct route, first class with lower berth or nearest equivalent.

      iii. Costs incurred for lodging, meals, and incidental expenses shall be considered reasonable and allowable to the extent that they do not exceed on a daily basis the per diem rates set forth in the Federal Travel Regulation (FTR).

      iv. Travel via privately owned automobile shall be reimbursed at not more than the current General Services Administration (GSA) FTR established mileage rate.

ARTICLE G.7. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

1. Contractor Performance Evaluations

Interim and final evaluations of Contractor performance will be prepared on this contract in accordance with FAR Subpart 42.1502. The final performance evaluation will be prepared at the time of completion of work. In addition to the final evaluation, an interim evaluation shall be submitted at least once during the

* Certain confidential information contained in this document, marked [***], is filed separately with the Securities and Exchange Commission.

contract period of performance. The interim evaluation is expected to be submitted on September 17, 2019.

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

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

2. **Electronic Access to Contractor Performance Evaluations**

The USG website for Contractor Performance Assessment Reporting System (CPARS) is http://www.cpars.gov. Through this website Contractors may access evaluations through a secure website for review and comment by completing the online registration form.

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

ARTICLE G.8. CONTRACT COMMUNICATIONS/CORRESPONDENCE

The Contractor shall identify all correspondence, reports, and other data pertinent to this contract by imprinting the contract number HHSO100201800029C from Page 1 of the contract.

ARTICLE G.10. OVERTIME COMPENSATION

No overtime (premium) compensation is authorized under this contract.

* Certain confidential information contained in this document, marked [***], is filed separately with the Securities and Exchange Commission.

SECTION H - SPECIAL CONTRACT REQUIREMENTS

The Contractor, depending upon the nature of the work, is responsible for following the provisions below in conducting its own work under this Contract. The Contractor also is responsible for incorporating these provisions into any subcontract awarded, if applicable to the specific nature of the work in the subcontract. Accordingly, those provisions shall be flowed- down as applicable.

ARTICLE H.1 NON-CLINICAL TERMS OF AWARD

BARDA has a responsibility to obtain documentation concerning mechanisms and procedures that are in place to protect the safety of participants and animals in BARDA funded clinical trials and non-clinical studies. Therefore, the Contractor shall develop a protocol for each clinical trial *and* non-clinical study funded under this contract and submit all such protocols and protocol amendments to the Contracting Officer's Representative (COR) for evaluation and comment.
Approval by the COR is required before work under a protocol may begin. The COR comments will be forwarded to the Contractor within ten (10) business days. The Contractor must address, in writing, all concerns (*e.g.* study design, safety, regulatory, ethical, and conflict of interest) noted by the COR.

If the draft protocols are to be submitted to the FDA, BARDA review shall occur before submission, pursuant to the terms set forth by ARTICLE F.2 of this contract. The Contractor shall consider revising their protocols to address BARDA's concerns and recommendations prior to FDA submission. The Contractor must provide BARDA with a copy of FDA submissions, within the time frame set forth by ARTICLE F.2 of this contract.

Execution of clinical and non-clinical studies requires written authorization from the government.

The USG will provide written authorization to the Contractor upon either 1) receiving documentation in which all COR comments have been satisfactorily addressed; or 2) receiving documentation that the FDA has reviewed and commented on the protocol.

* Certain confidential information contained in this document, marked [***], is filed separately with the Securities and Exchange Commission.

The government shall have rights to all protocols, data resulting from execution of these protocols, and final reports funded by BARDA under this contract, as set forth in PART II of this contract and defined in the FAR. The government reserves the right to request that the Contractor provide any contract deliverable in a non-proprietary form to ensure the government has the ability to review and distribute the deliverables as the government deems necessary.

Important information regarding performing human subject research is available at http://www3.niaid.nih.gov/healthscience/clinicalstudies/.

Any updates to technical reports are to be addressed in the Monthly and Annual Progress Reports. The Contractor shall advise the Contracting Officer's Representative or designee in writing and via electronic communication in a timely manner of any issues potentially affecting contract performance.

1. Non-Clinical Terms of Award

These Non-Clinical Terms of Award detail an agreement between the Biomedical Advanced Research and Development Authority (BARDA) and the Contractor; they apply to all grants and contracts that involve non-clinical research.

a. Safety and Monitoring Issues

i. PHS Policy on Humane Care and use of Laboratory Animals

Before award and then with the annual progress report, the Contractor must submit to BARDA a copy of the current Institutional Animal Care and Use Committees (IACUC) documentation of continuing review and approval and the Office of Laboratory Animal Welfare (OLAW) federal wide assurance number for the institution or site.

If other institutions are involved in the research (e.g., a multicenter trial or study), each institution's IACUC must review and approve the protocol. They must also provide BARDA initial and annual documentation of continuing review and approval and federal wide assurance number.

The Contractor must ensure that the applications, as well as all protocols, are reviewed by the performing institution's IACUC.

To help ensure the safety of animals used in BARDA-funded studies, the Contractor must provide BARDA copies of documents related to all major changes in the status of ongoing protocols, including the following:

- All amendments or changes to the protocol, identified by protocol version number, date, or both and date it is valid.
- All material changes in IACUC policies and procedures, identified by version number, date, and all required signatories (if applicable).

- Termination or temporary suspension of the study(ies) for regulatory issues.
- Termination or temporary suspension of the protocol.
- Any change that is made in the specific IACUC approval for the indicated study(ies).
- Any other problems or issues that could affect the scientific integrity of the study(ies), i.e., fraud, misrepresentation, misappropriation of funds, etc.

Contractor must notify BARDA of any of the above changes within five (5) working days from the time the Contractor becomes aware of such changes by email or fax, followed by a letter signed by the institutional business official, detailing notification of the change of status to the local IACUC and a copy of any responses from the IACUC.

If a non-clinical protocol has been reviewed by an institutional biosafety committee (IBC) or the NIH Recombinant DNA Advisory Committee (RAC), the Contractor must provide information about the initial and ongoing review and approval, if any. See the NIH Guidelines for Research Involving Recombinant DNA Molecules.

ii. Non-Clinical Data and Safety Monitoring Requirements

BARDA strongly recommends continued safety monitoring for all non- clinical studies of investigational drugs, devices, or biologics. FDA expects non-clinical studies to include safety in addition to efficacy. The Contractor should consider evaluation of clinical relevant safety markers in the pivotal and non-pivotal, non-clinical studies. In preparation for clinical trials of licensed or not yet licensed products, it is imperative that BARDA- sponsored studies of any type measure the risk and safety parameters that are elicited and provide a safety profile from the studies for future human risk assessment.

A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. For example, the risk of drawing a small amount of blood from a healthy subject for research purposes is no greater than the risk of doing so as part of a routine physical examination (45 CFR 46.102(i)).

BARDA will work with the Contractor on decisions regarding the type and extent of safety data accrual to be employed before the start of efficacy or safety studies.

The Contractor shall inform BARDA of any upcoming site visits and/or audits of CRO facilities funded under this effort. BARDA reserves the right to accompany the Contractor on site visits and/or audits of CRO is as BARDA deems necessary.

b. BARDA Review Process before Non-Clinical study Execution Begins

BARDA is under the same policy-driven assurances as NIH in that it has a responsibility to ensure that mechanisms and procedures are in place to protect the safety and welfare of animals used in BARDA-funded non-clinical trials. Therefore, before study execution, the Contractor must provide the following (as applicable) for review and comment by BARDA:

- IACUC approved (signed) non-clinical research protocol identified by version number, date, or both, including details of study design, euthanasia criteria, proposed interventions, and exclusion criteria.
- For non-pivotal mouse studies, the Contractor will provide an annual animal care and use protocol.
- Documentation of IACUC approval, including OLAW federal wide number, IACUC registration number, and IACUC name.
- Contractor should reduce the number of animals required for a study using power of statistics.
- Plans for the management of side effects, rules for interventions and euthanasia criteria.
- Procedures for assessing and collecting safety data were appropriate.
- If a study is contracted through Contract Research Organizations (CROs), work orders and service agreements the Contractor shall assure an integrated safety documentation plan is in place for the study site, pharmacy service records on the dosing material to be used and excipients, and laboratory services (including histopathology).
- Documentation that the Contractor and all required staff responsible for the conduct of the research have received training in the protection and handling of animals, or that the CRO has the required documentation.
- Purchasing of animals and/or other supplies for non-clinical studies funded in part or in whole by BARDA requires written approval by the Contracting Officer in accordance with the contract. The Contractor must have the ability to return/re-sell animals, at purchase price, to distributor or a third part, in the event that the Contracting Officer Authorization is not granted.
- Provide justification for whether studies require good laboratory practice (GLP) conditions.
- Provide justification for whether studies will be classified as non- pivotal or pivotal studies.

Documentation of each of the above items shall be submitted to BARDA for evaluation and comment in conjunction with the protocol. Execution of non- clinical

studies requires written authorization from the Contracting Officer in accordance with this section of the contract.

c. References

Public Health Service Policy on Humane Care and Use of Laboratory Animals:

http://grants.nih.gov/grants/olaw/InvestigatorsNeed2Know.pdf

USDA Animal Welfare Act:

http://awic.nal.usda.gov/nal_display/index.php?info_center=3&tax_level=3&tax_subject=182&topic_id=1118&level3_id=6735&level4_id=0&level5_id=0&placement_d default=0

ARTICLE H.2. CARE OF LIVE VERTEBRATE ANIMALS, HHSAR 352.270-5 (October 2009)

a. Before undertaking performance of any contract involving animal-related activities where the species is regulated by USDA, the Contractor shall register with the Secretary of Agriculture of the United States in accordance with 7 U.S.C. 2136 and 9 CFR sections 2.25 through 2.28. The Contractor shall furnish evidence of the registration to the Contracting Officer.

b. The Contractor shall acquire vertebrate animals used in research from a dealer licensed by the Secretary of Agriculture under 7 U.S.C. 2133 and 9 CFR Sections 2.1-2.11, or from a source that is exempt from licensing under those sections.

c. The Contractor agrees that the care, use and intended use of any live vertebrate animals in the performance of this contract shall conform with the Public Health Service (PHS) Policy on Humane Care of Use of Laboratory Animals (PHS Policy), the current Animal Welfare Assurance (Assurance), the Guide for the Care and Use of Laboratory Animals (National Academy Press, Washington, DC) and the pertinent laws and regulations of the United States Department of Agriculture (see 7 U.S.C. 2131 et seq. and 9 CFR Subchapter A, Parts 1-4). In case of conflict between standards, the more stringent standard shall govern.

d. If at any time during performance of this contract, the Contracting Officer determines, in consultation with the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), that the Contractor is not in compliance with any of the requirements and standards stated in paragraphs (a) through (c) above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may, in consultation with OLAW, NIH, terminate this contract in whole or in part, and the Contractor's name may be removed from the list of those contractors with approved Assurances.

Note: The Contractor may request registration of its facility and a current listing of licensed dealers from the Regional Office of the Animal and Plant Health Inspection Service

(APHIS), USDA, for the region in which its research facility is located. The location of the appropriate APHIS Regional Office, as well as information concerning this program may be obtained by contacting the Animal Care Staff, USDA/APHIS, 4700 River Road, Riverdale, Maryland 20737 (E-mail: ace@aphis.usda.gov;W eb site: (http://www.aphis.usda.gov/animal_welfare).

* Certain confidential information contained in this document, marked [***], is filed separately with the Securities and Exchange Commission.

ARTICLE H.3. ANIMAL WELFARE

All research involving live, vertebrate animals shall be conducted in accordance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals. This policy may be accessed at:

http://grants1.nih.gov/grants/olaw/references/phspol.htm

ARTICLE H.4. INFORMATION ON COMPLIANCE WITH ANIMAL CARE REQUIREMENTS

Registration with the U. S. Dept. of Agriculture (USDA) is required to use regulated species of animals for biomedical purposes. USDA is responsible for the enforcement of the Animal Welfare Act (7 U.S.C. 2131 et. seq.), http://www.nal.usda.gov/awic/legislat/awa.htm.

The Public Health Service (PHS) Policy is administered by the Office of Laboratory Animal Welfare (OLAW) http://grants2.nih.gov/grants/olaw/olaw.htm. An essential requirement of the PHS Policy http://grants2.nih.gov/grants/olaw/references/phspol.htm is that every institution using live vertebrate animals must obtain an approved assurance from OLAW before they can receive funding from any component of the U. S. Public Health Service.

The PHS Policy requires that Assured institutions base their programs of animal care and use on the Guide for the Care and Use of Laboratory Animals http://www.nap.edu/readingroom/books/labrats/ and that they comply with the regulations (9 CFR, Subchapter A)http://www.nal.usda.gov/awic/legislat/usdaleg1.htm issued by the U.S. Department of Agriculture (USDA) under the Animal Welfare Act. The Guide may differ from USDA regulations in some respects. Compliance with the USDA regulations is an absolute requirement of this Policy.

The Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) http://www.aaalac.org is a professional organization that inspects and evaluates programs of animal care for institutions at their request. Those that meet the high standards are given the accredited status. As of the 2002 revision of the PHS Policy, the only accrediting body recognized by PHS is the AAALAC. While AAALAC Accreditation is not required to conduct biomedical research, it is highly desirable. AAALAC uses the Guide as their primary evaluation tool. They also use the Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching. It is published by the Federated of Animal Science Societies http://www.fass.org.

ARTICLE H.5. REQUIREMENTS FOR ADEQUATE ASSURANCE OF PROTECTION OF VERTEBRATE ANIMAL SUBJECTS

The PHS Policy on Humane Care and Use of Laboratory Animals requires that applicant organizations proposing to use vertebrate animals file a written Animal Welfare Assurance with the Office for Laboratory Animal Welfare (OLAW), establishing appropriate policies and procedures to ensure the humane care and use of live vertebrate animals involved in research activities supported by the PHS. The PHS Policy stipulates that an applicant organization, whether domestic or foreign, bears responsibility for the humane care and use of animals in PHS- supported research activities. Also, the PHS policy defines “animal” as “any live, vertebrate animal used, or intended for use, in research, research training, experimentation, biological testing or for related purposes.” This Policy implements and supplements the U.S. government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training, and requires that institutions use the Guide for the Care and Use of Laboratory Animals as a basis for developing and implementing an institutional animal care and use program. This Policy does not affect applicable State or local laws or regulations that

impose more stringent standards for the care and use of laboratory animals. All institutions are required to comply, as applicable, with the Animal Welfare Act as amended (7 USC 2131 et. seq.) and other Federal statutes and regulations relating to animals. These documents are available from the Office of Laboratory Animal Welfare, National Institutes of Health, Bethesda, MD 20892, (301) 496-7163. See http://grants.nih.gov/grants/olaw/olaw.htm.

No PHS supported work for research involving vertebrate animals will be conducted by an organization, unless that organization is operating in accordance with an approved Animal Welfare Assurance and provides verification that the Institutional Animal Care and Use Committee (IACUC) has reviewed and approved the proposed activity in accordance with the PHS policy. Applications may be referred by the PHS back to the institution for further review in the case of apparent or potential violations of the PHS Policy. No award to an individual will be made unless that individual is affiliated with an assured organization that accepts responsibility for compliance with the PHS Policy. Foreign applicant organizations applying for PHS awards for activities involving vertebrate animals are required to comply with PHS Policy or provide evidence that acceptable standards for the humane care and use of animals will be met. Foreign applicant organizations are not required to submit IACUC approval, but should provide information that is satisfactory to the USG to provide assurances for the humane care of such animals.

ARTICLE H.6. APPROVAL OF REQUIRED ASSURANCE BY OLAW

Under governing regulations, federal funds which are administered by the Department of Health and Human Services, Office of Biomedical Advanced Research and Development Authority (BARDA) shall not be expended by the Contractor for research involving live vertebrate animals, nor shall live vertebrate animals be involved in research activities by the Contractor under this award unless a satisfactory assurance of compliance with 7 U.S.C. 2316 and 9 CFR Sections 2.25-2.28 is submitted within 30 days of the date of this award and approved by the Office of Laboratory Animal Welfare (OLAW). Each performance site (if any) must also assure compliance with 7 U.S.C. 2316 and 9 CFR Sections 2.25-2.28 with the following restriction: Only activities which do not directly involve live vertebrate animals (i.e. are clearly severable and independent from those activities that do involve live vertebrate animals) may be conducted by the Contractor or individual performance sites pending OLAW approval of their respective assurance of compliance with 7 U.S.C. 2316 and 9 CFR Sections 2.25-2.28. Additional information regarding OLAW may be obtained via the Internet at http://grants2.nih.gov/grants/olaw/references/phspol.htm

ARTICLE H.7. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

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

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

ARTICLE H.8. PROHIBITION ON CONTRACTOR INVOLVEMENT WITH TERRORIST ACTIVITIES

The Contractor acknowledges that U.S. Executive Orders and Laws, including but not limited to

E.O. 13224 and P.L. 107-56, prohibit transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. It is the legal responsibility of the Contractor to ensure compliance with these Executive Orders and Laws. This clause must be included in all subcontracts issued under this contract.

* Certain confidential information contained in this document, marked [***], is filed separately with the Securities and Exchange Commission.

ARTICLE H.9. IDENTIFICATION AND DISPOSITION OF DATA

The Contractor will be required to provide certain data generated under this contract to the Department of Health and Human Services (DHHS). DHHS reserves the right to review any other data determined by DHHS to be relevant to this contract. The contractor shall keep copies of all data required by the Food and Drug Administration (FDA) relevant to this contract for the time specified by the FDA.

ARTICLE H.10. EXPORT CONTROL NOTIFICATION

Contractors are responsible for ensuring compliance with all export control laws and regulations that may be applicable to the export of and foreign access to their proposed technologies.
Contractors may consult with the Department of State with any questions regarding the International Traffic in Arms Regulation (ITAR) (22 CRF Parts 120-130) and /or the Department of Commerce regarding the Export Administration Regulations (15 CRF Parts 730-774).

ARTICLE H.11. CONFLICT OF INTEREST

The Contractor represents and warrants that, to the best of the Contractor's knowledge and belief, there are no relevant facts or circumstances which could give rise to an organizational conflict of interest, as defined in FAR 2.101 and Subpart 9.5, or that the Contractor has disclosed all such relevant information. Prior to commencement of any work, the Contractor agrees to notify the Contracting Officer promptly that, to the best of its knowledge and belief, no actual or potential conflict of interest exists or to identify to the Contracting Officer any actual or potential conflict of interest the firm may have. In emergency situations, however, work may begin but notification shall be made within five (5) working days. The Contractor agrees that if an actual or potential organizational conflict of interest is identified during performance, the Contractor shall promptly make a full disclosure in writing to the Contracting Officer. This disclosure shall include a description of actions which the Contractor has taken or proposes to take, after consultation with the Contracting Officer, to avoid, mitigate, or neutralize the actual or potential conflict of interest. The Contractor shall continue performance until notified by the Contracting Officer of any contrary action to be taken. Remedies include termination of this contract for convenience, in whole or in part, if the Contracting Officer deems such termination necessary to avoid an organizational conflict of interest. If the Contractor was aware of a potential organizational conflict of interest prior to award or discovered an actual or potential conflict after award and did not disclose it or misrepresented relevant information to the Contracting Officer, the USG may terminate the contract for default, debar the Contractor from USG contracting, or pursue such other remedies as may be permitted by law or this contract.

ARTICLE H.12. INSTITUTIONAL RESPONSIBILITY REGARDING INVESTIGATOR FINANCIAL CONFLICTS OF INTEREST

The Contractor shall comply with the requirements of 45 CFR Part 94, Responsible Prospective Contractors, which promotes objectivity in research by establishing standards to ensure that Investigators (defined as the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded under BARDA contracts, or proposed for such funding, which may include, for example, collaborators or consultants) will not be biased by any Investigator financial conflicts of interest.

If the failure of an Investigator to comply with an Institution's financial conflicts of interest policy or a financial conflict of interest management plan appears to have biased the design,

conduct, or reporting of the BARDA-funded research, the Contractor must promptly notify the Contracting Officer of the corrective action taken or to be taken. The Contracting Officer will consider the situation and, as necessary, take appropriate action or refer the matter to the Contractor for further action, which may include directions to the Contractor on how to maintain appropriate objectivity in the BARDA-funded research project.

The Contracting Officer and/or HHS may inquire at any time before, during, or after award into any Investigator disclosure of financial interests, and the Contractor's review of, and response to, such disclosure, regardless of whether the disclosure resulted in the Contractor's determination of a financial conflict of interests. The Contracting Officer may require submission of the records or review them on site. On the basis of this review of records or other information that may be available, the Contracting Officer may decide that a particular financial conflict of interest will bias the objectivity of the BARDA-funded research to such an extent that further corrective action is needed or that the Institution has not managed the financial conflict of interest in accordance with 45 CFR Part 94. The issuance of a Stop Work Order by the Contracting Officer may be necessary until the matter is resolved.

If the Contracting Officer determines that BARDA-funded clinical research, whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, has been designed, conducted, or reported by an Investigator with a financial conflict of interest that was not disclosed managed or reported the Contractor shall require the Investigator involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

ARTICLE H.13. NEEDLE DISTRIBUTION

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

ARTICLE H.14. RESTRICTION ON ABORTIONS

The Contractor shall not use contract funds for any abortion.

ARTICLE H.15. CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH

The Contractor shall not use contract funds for (1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.204(b) and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)). The term "human embryo or embryos" includes any organism, not protected

as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

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

ARTICLE H.16. DISSEMINATION OF FALSE OR DELIBERATELY MISLEADING INFORMATION

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

ARTICLE H.17. CONFIDENTIALITY OF INFORMATION

a. Confidential information, as used in this article, means information or data of a personal nature about an individual or proprietary information or data submitted by or pertaining to an institution or organization.

b. The Contracting Officer and the Contractor may, by mutual consent, identify elsewhere in this contract specific information and/or categories of information which the USG will furnish to the Contractor or that the Contractor is expected to generate which is confidential and providing further that the government is not entitled to unlimited rights to that information pursuant to FAR 52.227-14. Similarly, the Contracting Officer and the Contractor may, by mutual consent, identify such confidential information from time to time during the performance of the contract. Failure to agree will be settled pursuant to the "Disputes" clause.

c. If it is established elsewhere in this contract that information to be utilized under this contract, or a portion thereof, is subject to the Privacy Act, the Contractor will follow the rules and procedures of disclosure set forth in the Privacy Act of 1974, 5 U.S.C. 552a, and implementing regulations and policies, with respect to systems of records determined to be subject to the Privacy Act.

d. Confidential information, as defined in paragraph (a) of this article, shall not be disclosed without the prior written consent of the individual, institution, or organization.

e. Whenever the Contractor is uncertain with regard to the proper handling of material under the contract, or if the material in question is subject to the Privacy Act or is confidential information subject to the provisions of this article, the Contractor should obtain a written determination from the Contracting Officer prior to any release, disclosure, dissemination, or publication.

f. The provisions of paragraph (d) of this article shall not apply to conflicting or overlapping provisions in other Federal, State or local laws.

ARTICLE H.18. ACCESS TO DOCUMENTATION/DATA

The USG shall have physical and electronic access to all documentation and data generated under this contract, including: all data documenting Contractor performance; all data generated; all communications and correspondence with regulatory agencies and bodies to include all audit observations, inspection reports, milestone completion documents, and all Offeror commitments and responses. Contractor shall provide the USG with an electronic copy of all correspondence with the FDA within 5 business days of receipt. The USG shall acquire unlimited rights to all data f u n d e d under this contract in accordance with FAR Subpart 27.4 and FAR Clause 52.227- 14.

ARTICLE H.19. EPA ENERGY STAR REQUIREMENTS

In compliance with Executive Order 12845 (requiring Agencies to purchase energy efficient computer equipment), all microcomputers, including personal computers, monitors, and printers that are purchased using USG funds in performance of a contract shall be equipped with or meet the energy efficient low-power standby feature as defined by the EPA Energy Star program unless the equipment always meets EPA Energy Star efficiency levels. The microcomputer, as configured with all components, must be Energy Star compliant.

This low-power feature must already be activated when the computer equipment is delivered to the agency and be of equivalent functionality of similar power managed models. If the equipment will be used on a local area network, the vendor must provide equipment that is

fully compatible with the network environment. In addition, the equipment will run commercial off-the-shelf software both before and after recovery from its energy conservation mode.

ARTICLE H.20. ACKNOWLEDGMENT OF FEDERAL FUNDING

Section 507 of P.L. 104-208 mandates that Contractors funded with Federal dollars, in whole or in part, acknowledge Federal funding when issuing statements, press releases, requests for proposals, bid solicitations and other documents. This requirement is in addition to the continuing requirement to provide an acknowledgment of support and disclaimer on any publication reporting the results of a contract funded activity.

A. **Publication and Publicity**

No information related to data obtained under this contract shall be released or publicized without providing BARDA with at least thirty (30) days advanced notice and an opportunity to review the proposed release or publication.

In addition to the requirements set forth in HHSAR Clause 352.227-70, Publications and Publicity incorporated by reference in SECTION I of this contract, Section 507 of
P.L. 104-208 mandates that Contractors funded with Federal dollars, in whole or in part, acknowledge Federal funding when issuing statements, press releases, requests for proposals, bid solicitations and other documents. Contractors are required to state:

(1) the percentage and dollar amounts of the total program or project costs financed with Federal money and;
(2) the percentage and dollar amount of the total costs financed by nongovernmental sources

For purposes of this contract "publication" is defined as an issue of printed material offered for distribution or any communication or oral presentation of information, including any manuscript or scientific meeting abstract. Any publication containing data generated under this contract must be submitted for BARDA review no less than thirty (30) calendar days for manuscripts and fifteen (15) calendar days for abstracts before submission for public presentation or publication. Contract support shall be acknowledged in all such publications substantially as follows:

"This project has been funded in whole or in part with Federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, under Contract No. HHSO100201800029C."

B. **Press Releases**

Misrepresenting contract results or releasing information that is injurious to the integrity of BARDA may be construed as improper conduct. Press releases shall be considered to include the public release of information to any medium, excluding peer-reviewed scientific publications. The contractor shall ensure that the COR has received an advance copy of any press release related to the contract not less than six (6) business days prior to the issuance of the press release.

The Contractor shall acknowledge the support of the Department of Health and Human Service, Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

"This project has been funded in whole or in part with Federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, under Contract No. HHSO100201800029C."

ARTICLE H.21. IN-PROCESS REVIEW

In Process Reviews (IPR) will be conducted at the discretion of the USG to discuss the progression of the milestones. The USG reserves the right to revise the milestones and budget pending the development of the project. Deliverables such as an overall project summary report and/or slides will be required when the IPRs are conducted. The Contractor's success in completing the required tasks under each work segment must be demonstrated through the Deliverables and Milestones specified under SECTION F. Those deliverables will constitute the basis for the USG's decision, at its sole discretion, to proceed with the work segment, or institute changes to the work segment, or terminate the work segment.

IPRs may be scheduled at the discretion of the USG to discuss progression of the contract. The Contractor shall provide a presentation following a prescribed template which will be provided by the USG at least 30 business days prior to the IPR. Subsequently, the contractor will be requested to provide a revised/final presentation to the Contracting Officer at least 10 business days prior to the IPR.

ARTICLE H.22. PROHIBITION ON THE USE OF APPROPRIATED FUNDS FOR LOBBYING ACTIVITIES AND HHSAR 352.203-70 ANTI-LOBBYING (March 2012))

The Contractor is hereby notified of the restrictions on the use of Department of Health and Human Service's funding for lobbying of Federal, State and Local legislative bodies.

Section 1352 of Title 10, United Stated Code (Public Law 101-121, effective 12/23/89), among other things, prohibits a recipient (and their subcontractors) of a Federal contract, grant, loan, or cooperative agreement from using appropriated funds (other than profits from a federal contract) to pay any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with any of the following covered Federal actions; the awarding of any Federal contract; the making of any Federal grant; the making of any Federal loan; the entering into of any cooperative agreement; or the modification of any Federal contract, grant, loan, or cooperative agreement. For additional information of prohibitions against lobbying activities, see FAR Subpart 3.8 and FAR Clause 52.203-12.

In addition, as set forth in HHSAR 352.203-70 "Anti-Lobbying" (March 2012)), the current Department of Health and Human Services Appropriations Act provides that no part of any appropriation contained in this Act shall be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support, or defeat legislation pending before the Congress, or any State or Local legislature except in presentation to the Congress, or any State or Local legislative body itself.

The current Department of Health and Human Services Appropriations Act also provides that no part of any appropriation contained in this Act shall be used to pay the salary or expenses of any contract or grant recipient, or agent acting for such recipient, related to any activity designed to influence legislation or appropriations pending before the Congress, or any State or Local legislature.

* Certain confidential information contained in this document, marked [***], is filed separately with the Securities and Exchange Commission.

ARTICLE H.23. PRIVACY ACT APPLICABILITY

1) Notification is hereby given that the Contractor and its employees are subject to criminal penalties for violation of the Privacy Act to the same extent as employees of the USG. The Contractor shall assure that each of its employees knows the prescribed rules of conduct and that each is aware that he or she can be subjected to criminal penalty for violation of the Act. A copy of 45 CFR Part 5b, Privacy Act Regulations, may be obtained at http://www.gpoaccess.gov/cfr/index.html

2) The Project Officer is hereby designated as the official who is responsible for monitoring contractor compliance with the Privacy Act.

3) The Contractor shall follow the Privacy Act guidance as contained in the Privacy Act System of Records number 09-25-0200. This document may be obtained at the following link: http://oma.od.nih.gov/ms/privacy/pa-files/0200.htm

ARTICLE H.24. LABORATORY LICENSE REQUIREMENTS

The Contractor shall comply with all applicable requirements of Section 353 of the Public Health Service Act (Clinical Laboratory Improvement Act as amended) (42 U.S.C. 263a and 42 CFR Part 493). This requirement shall also be included in any subcontract for services under the contract.

ARTICLE H.25. QUALITY ASSURANCE (QA) AUDIT REPORTS

BARDA reserves the right to participate in QA audits. Upon completion of the audit/site visit the Contractor shall provide a report capturing the findings, results and next steps in proceeding with the subcontractor. If action is requested of the subcontractor, detailed concerns for addressing areas of non-conformance to FDA regulations for GLP, GMP, or GCP guidelines, as identified in the audit report, must be provided to BARDA. The Contractor shall provide responses from the subcontractors to address these concerns and plans for corrective action execution.

- Contractor shall notify CO and COR of upcoming, ongoing, or recent audits/site visits of subcontractors as part of weekly communications
- Contractor shall notify the COR and CO within 5 business days of report completion.

ARTICLE H.26. BARDA AUDITS

Contractor shall accommodate periodic or ad hoc site visits by the USG. If the USG, the Contractor, or other parties identifies any issues during an audit, the Contractor shall capture the issues, identify potential solutions, and provide a report to the USG.

- If issues are identified during the audit, Contractor shall submit a report to the CO and COR detailing the finding and corrective action(s) within 10 business days of the audit.
- COR and CO will review the report and provide a response to the Contractor with 10 business days.
- Once corrective action is completed, the Contractor will provide a final report to the CO and COR.

ARTICLE H.27. SECURITY REPORTING REQUIREMENT

Violations of established security protocols shall be reported to the Contracting Officer (CO) and Contracting Officer's Representative (COR) upon discovery and within 24 hours of any

compromise, intrusion, loss or interference of its security processes and procedures. The Contractor shall ensure that all software components that are not required for the operation and maintenance of the database/control system has been removed and/or disabled. The Contractor shall provide to the CO and the COR information appropriate to Information and Information Technology software and service updates and/or workarounds to mitigate all vulnerabilities associated with the data and shall maintain the required level of system security.

The Contractor will investigate violations to determine the cause, extent, loss or compromise of sensitive program information, and corrective actions taken to prevent future violations. The Contracting Officer in coordination with BARDA will determine the severity of the violation. Any contractual actions resulting from the violation will be determined by the Contracting Officer.

ARTICLE H.28. RESTRICTION ON EMPLOYMENT OF UNAUTHORIZED ALIEN WORKERS

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

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

ARTICLE H.29. NOTIFICATION OF CRITICAL PROGRAMMATIC CONCERNS, RISKS, OR POTENTIAL RISKS

If any action occurs that creates a cause for critical programmatic concern, risk, or potential risk to BARDA or the Contractor and Incident Report shall be delivered to BARDA.

- Within 48 hours of activity or incident or within 24 hours 24 hours for a security related activity or incident, Contractor must notify BARDA.
- Additional updates due to COR and CO within 48 hours of additional developments.
- Contractor shall submit within 5 business days a Corrective Action Plan (if deemed necessary by either party) to address any potential issues.

If corrective action is deemed necessary, Contractor must address in writing, its consideration of concerns raised by BARDA within 5 business days.

ARTICLE H.31. PERSON IN PLANT

With seven (7) business days advance notice to the Contractor in writing from the Contracting Officer, the USG may place a person-in-plant in the Contractor's or subcontractor's or subcontractor's facility, who and facility access at all times while in the facility.

An article substantially similar to this Person-in-Plant article shall be incorporated into any subcontract for experimental or manufacturing work.

* Certain confidential information contained in this document, marked [***], is filed separately with the Securities and Exchange Commission.

PART II - CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

ARTICLE I.1. FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)

This contract incorporates the following clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at these addresses: https://www.acquisition.gov/FAR/ . HHSAR Clauses at: http://www.hhs.gov/policies/hhsar/subpart352.html .

FEDERAL ACQUISIITON REGULATION (48 CFR CHAPTER 1) CLAUSE:

52.242-15, Stop Work Order (August 1989)

Clauses for Cost-Reimbursement Research and Development Contract

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

FAR CLAUSE	DATE	CLAUSE TITLE
52.202-1	Nov 2013	Definitions
52.203-3	Apr 1984	Gratuities
52.203-5	May 2014	Covenant Against Contingent Fees
52.203-6	Sep 2006	Restrictions on Subcontractor Sales to the government
52.203-7	May 2014	Anti-Kickback Procedures
52.203-8	May 2014	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity
52.203-10	May 2014	Price or Fee Adjustment for Illegal or Improper Activity
52.203-12	Oct 2010	Limitation on Payments to Influence Certain Federal Transactions
52.203-13	Apr 2010	Contractor Code of Business Ethics and Conduct
52.203-17	April 2014	Contractor Employee Whistleblower Rights and Requirements to Inform Employees of Whistleblower rights
52.204-4	May 2011	Printed or Copied Double-Sided on Recycled Paper
52.204-7	Jul 2013	System for Award Management
52.204-10	Jul 2013	Reporting Executive Compensation and First-Tier Subcontract Awards
52.204-13	Jul 2013	System for Award Management Maintenance

* Certain confidential information contained in this document, marked [***], is filed separately with the Securities and Exchange Commission.

52.209-6	Aug 2013	Protecting the government's Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment
52.209-9	Jul 2013	Updates of Publicly Available Information Regarding Responsibility Matters
52.210-1	Apr 2011	Market Research
52.215-2	Oct 2010	Audit and Records – Negotiation
52.215-8	Oct 1997	Order of Precedence - Uniform Contract Format
52.215-10	Aug 2011	Price Reduction for Defective Certified Cost or Pricing Data
52.215-12	Oct 2010	Subcontractor Certified Cost or Pricing Data
52.215-15	Oct 2010	Pension Adjustments and Asset Reversions
52.215-17	Oct 1997	Facilities Capital Cost of Money
52.215-18	Jul 2005	Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) other than Pensions
52.215-19	Oct 1997	Notification of Ownership Changes
52.215-21	Oct 2010	Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data – Modifications
52.215-23	Oct 2009	Limitations on Pass-Through Charges
52.216-7	Jun 2013	Allowable Cost and Payment
52.216-8	Jun 2011	Fixed Fee
52.217-8	Nov 1999	Option to Extend Services
52.219-8	Oct 2014	Utilization of Small Business Concerns
52.222-2	Jul 1990	Payment for Overtime Premiums
52.222-3	Jun 2003	Convict Labor
52.222-21	Apr 2015	Prohibition of Segregated Facilities
52.222-26	Apr 2015	Equal Opportunity
52.222-35	Jul 2014	Equal Opportunity for Veterans
52.222-36	Jul 2014	Equal Opportunities for Workers with Disabilities
52.222-37	Jul 2014	Employment Reports on Veterans
52.222-40	Dec 2010	Notification of Employee Rights Under the National Labor Relations Act
52.222-50	Mar 2015	Combating Trafficking in Persons
52.222-54	Aug 2013	Employment Eligibility Verification
52.223-6	May 2001	Drug-Free Workplace
52.223-18	Aug 2011	Encouraging Contractor Policies to Ban Text Messaging While Driving

* Certain confidential information contained in this document, marked [***], is filed separately with the Securities and Exchange Commission.

52.224-1	April 1984	Privacy Act Notification
52.224-2	April 1984	Privacy Act
52.225-13	Jun 2008	Restrictions on Certain Foreign Purchases
52.227-1	Dec 2007	Authorization and Consent, Alternate I
52.227-2	Dec 2007	Notice and Assistance Regarding Patent and Copyright Infringement
52.227-3	April 1984	Patent Indemnity
52.227-11	May 2014	Patent Rights - Ownership by the Contractor (Note: In accordance with FAR 27.303(b)(2), paragraph (e) is modified to include the requirements in FAR 27.303(b)(2)(i) through (iv). The frequency of reporting in (i) is annual.)
52.227-14	May 2014	Rights in Data – General, Alt II
52.227-16	Jun 1987	Additional Data Requirements
52.232-9	Apr 1984	Limitation on Withholding of Payments
52.232-17	May 2014	Interest
52.232-20	Apr 1984	Limitation of Cost
52.232-23	May 2014	Assignment of Claims
52.232-25	Jun 2013	Prompt Payment Alternate I (Feb 2002)
52.232-33	Jul 2013	Payment by Electronic Funds Transfer--System for Award Management
52.233-1	May 2014	Disputes
52.233-3	Aug 1996	Protest After Award, Alternate I (June 1985)
52.233-4	Oct 2004	Applicable Law for Breach of Contract Claim
52.242-1	Apr 1984	Notice of Intent to Disallow Costs
52.242-3	May 2014	Penalties for Unallowable Costs
2.242-4	Jan 1997	Certification of Final Indirect Costs
52.242-13	Jul 1995	Bankruptcy
52.243-2	Aug 1987	Changes - Cost Reimbursement, Alternate V (Apr 1984)
52.244-2	Oct 2010	Subcontracts, Alternate I (Jun 2007)
52.244-5	Dec 1996	Competition in Subcontracting
52.244-6	Apr 2015	Subcontracts for Commercial Items
52.245-1	Apr 2012	Government Property
52.245-9	Apr 2012	Use and Charges
52.246-9	Apr 1984	Inspection of Research and Development (Short Form)
52.246-23	Feb 1997	Limitation of Liability

* Certain confidential information contained in this document, marked [***], is filed separately with the Securities and Exchange Commission.

52.246-25	Feb 1997	Limitation of Liability – Services
52.247-63	Jun 2003	Preference for U.S.-Flag Air Carriers
52.247-67	Feb 2006	Submission of Transportation Documents for Audit
52.249-6	May 2004	Termination (Cost-Reimbursement)
52-249-14	Apr 1984	Excusable Delays
52.251-1	Apr 2012	Government Supply Sources
52.253-1	Jan 1991	Computer Generated Forms

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

HHSAR CLAUSE NO.	DATE	TITLE
352.201-70	Jan 2006	Paperwork Reduction Act
352.202-1	Jan 2006	Definitions, with Alternate paragraph (h)
352.203-70	Mar 2012	Anti-Lobbying
352.216-70	Jan 2006	Additional Cost Principles
352.222-70	Jan 2010	Contractor Cooperation in Equal Employment Opportunity Investigations
352.223-70	Jan 2006	Safety and Health
352.224-70	Jan 2006	Privacy Act
352.227-70	Jan 2006	Publications and Publicity
352.228-7	Dec 1991	Insurance - Liability to Third Persons
352.231-70	Aug 2012	Salary Rate Limitation
352.233-71	Jan 2006	Litigation and Claims
352.242-70	Jan 2006	Key Personnel
352.242-73	Jan 2006	Withholding of Contract Payments
352.242-74	Apr 1984	Final Decisions on Audit Findings
352.270-4	Jan 2006	Protection of Human Subjects

ARTICLE I.2. ADDITIONAL CONTRACT CLAUSES

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

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

ARTICLE I.3. ADDITIONAL FAR CLAUSES INCLUDED IN FULL TEXT

FAR 52.217-9 Option to Extend the Term of the Contract

OPTION TO EXTEND THE TERM OF THE CONTRACT (MAR 2000)

(a) The government may extend the term of this contract by written notice to the Contractor within 15 days of the date the contract expires; provided that the government gives the

* Certain confidential information contained in this document, marked [***], is filed separately with the Securities and Exchange Commission.

Contractor a preliminary written notice of its intent to extend at least 60 days before the contract expires. The preliminary notice does not commit the government to an extension.

(b) If the government exercises this option, the extended contract shall be considered to include this option clause.

(c) The total duration of this contract, including base contract and the exercise of any options under this clause, shall not exceed seventy-three (73) months.

FAR 52.219-1 Small Business Program Representations

SMALL BUSINESS PROGRAM REPRESENTATIONS (OCT 2014)

(b) (1) The North American Industry Classification System (NAICS) code for this acquisition is 325413.

(2) The small business size standard is 500 employees.

(3) The small business size standard for a concern which submits an offer in its own name, other than on a construction or service contract, but which proposes to furnish a product which it did not itself manufacture, is 500 employees.

(c) *Representations*.

(1) The offeror represents as part of its offer that it [X] is, [ ] is not a small business concern.
(2) The offeror represents as part of its offer that it [ ] is, [X] is not, a small disadvantaged business concern as defined in 13 CFR 124.1002.
(3) The offeror represents as part of its offer that it [ ] is, [X] is not a woman-owned small business concern.

FAR 52.219-28, Post-Award Small Business Program Representation

POST-AWARD SMALL BUSINESS PROGRAM REPRESENTATION (JUL 2013)

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

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

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

* Certain confidential information contained in this document, marked [***], is filed separately with the Securities and Exchange Commission.

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

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

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

(3) For long-term contracts--

(i) Within 60 to 120 days prior to the end of the fifth year of the contract; and
(ii) Within 60 to 120 days prior to the date specified in the contract for exercising any option thereafter.

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

(d) The small business size standard for a Contractor providing a product which it does not manufacture itself, for a contract other than a construction or service contract, is 500 employees.
(e) Except as provided in paragraph (g) of this clause, the Contractor shall make the representation required by paragraph (b) of this clause by validating or updating all its representations in the Online Representations and Certifications Application and its data in the Central Contractor Registration, as necessary, to ensure that they reflect the Contractor's current status. The Contractor shall notify the contracting office in writing within the timeframes specified in paragraph (b) of this clause that the data have been validated or updated, and provide the date of the validation or update.

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

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

The Contractor represents that it [X] is, [] is not a small business concern under NAICS Code 325413 assigned to contract number HHSO100201800000C.

FAR 52.232-40, Providing Accelerated Payment to Small Business Subcontractors

PROVIDING ACCELERATED PAYMENT TO SMALL BUSINESS SUBCONTRACTORS (DEC 2013)

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

* Certain confidential information contained in this document, marked [***], is filed separately with the Securities and Exchange Commission.

(b) The acceleration of payments under this clause does not provide any new rights under the Prompt Payment Act.

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

* Certain confidential information contained in this document, marked [***], is filed separately with the Securities and Exchange Commission.

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

* Certain confidential information contained in this document, marked [***], is filed separately with the Securities and Exchange Commission.

SECTION J - LIST OF ATTACHMENTS

The following documents are attached and incorporated in this contract:

1. Statement of Work, dated September 19, 2018 (6 pages).
2. [***] (1 page)
3. Milestones/Deliverables and Technical Deliverables (1 page)
4. Invoice/Financing Request Instructions and Contract Financial Reporting Instructions for Cost-Reimbursement Type Contracts (5 pages).

PART IV - REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS AND CERTIFICATIONS

The following documents are incorporated by reference in this contract:

1. Annual Representations and Certifications completed and located at the System for Award Management website (SAM.gov).
2. Animal Welfare Assurance – No Animal Studies will be conducted at Opiant Pharmaceutical facilities. Animal Welfare Assurance Numbers will be procured from any subcontractors.

End of Contract No. HHSO100201800029C

ATTACHMENT 1

Statement of Work September 19, 2018

DEVELOPMENT OF A RAPID ACTING, LONG DURATION INTRANASAL ANTAGONIST TO REVERSE OPIOID (e.g. FENTANYL) OVERDOSE

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

Overall Objectives and Scope

The overall objective of this contract is to advance the development of nalmefene nasal spray as a rapid acting, potent, and long duration opioid antagonist for the treatment of opioid overdose.

This R&D effort for nalmefene nasal spray will progress in specific stages that cover the base performance segment (I) A Human Use Characteristics (clinical) study of nalmefene nasal spray (CLIN 0001), and the following option segments: (II) CMC activities: clinical batch manufacture and clinical batch stability (CLIN 0002); and (III) Regulatory activities: NDA preparation and NDA filing (CLIN 0003). When scope of work is completed, a product/package ready for NDA filing will result.

Development Approach

1.0 CLIN 0001 / Base Period

1.1 Program Management

1.1.1 Technical Project Management

Management of the subcontractors, risk and updates with program and contract officials.

1.1.2 Subcontractor management plan

Establish interaction for progress updates and risk management.

1.1.3 Risk management plan

Finalize risk management plan identifying key risks, mitigations and contingencies.

1.1.4 Project manager hire

Identify and hire a pharmaceutical project manager.

1.2 Clinical

1.2.1 Human Use Characteristics (human factors and usability studies)

[***]

2.0 CLIN 0002 / Option 1 Period

2.1 Program Management

2.1.1 Technical Project Management

Management of the subcontractors, risk and updates with program and contract officials.

2.2 CMC

[***]

2.2.1 Registration batch manufacture of nalmefene nasal spray

[***]

2.2.2 Registration batch stability studies

[***]

3.0 CLIN 0003 / Option 2 Period

3.1 Program Management

3.1.1 Technical Project Management

Management of the subcontractors, risk and updates with program and contract officials.

3.2 Regulatory

3.2.1 New Drug Application (NDA) for nalmefene nasal spray: preparation

[***]

3.2.2 New Drug Application: Filing

[***]

---End of Statement of Work---

* Certain confidential information contained in this document, marked [***], is filed separately with the Securities and Exchange Commission.

Attachment 2 – [***]

* Certain confidential information contained in this document, marked [***], is filed separately with the Securities and Exchange Commission.

ATTACHMENT 3 – MILESTONES AND DELIVERABLES CHART

Mstn #	GO/NO GO Contract Milestones	Go Criteria	No-Go Criteria	Deliverable	SOW/WBS #	CLIN initiated by Milestone Success
CLIN 0001	Completion of human factors and usability studies	Successful demonstration of ease of use of the intranasal device	Unable to demonstrate ease of use of the intranasal device	Study protocol and final study report	1.2.1	Required to initiate CLIN 0002
	Completion of dose formulation and clinical batch manufacture in NIDA grant	Successful identification of dose formulation, device and process requirements to use in the intranasal device	Unable to identity of a dose formulation, device and/or process requirements to use in the intranasal device	Final study report	N/A	Required to initiate CLIN 0002
CLIN 0002	Completion of manufacture and stability of registration batch material	Successful manufacture of material and demonstration of at least twelve month stability in accordance with ICH requirements	Unable to manufacture the material and/or demonstrate twelve month stability in accordance with ICH requirements	Batch and stability report	2.2.1 2.2.2	Required to initiate CLIN 0003
	Completion of nonclinical and clinical studies from NIDA grant	Acceptable toxicity issues and achievement of pilot study PK results in a larger pivotal study	Unacceptable toxicity issues and/or unable to repeat pilot study PK results in a larger clinical study	Final study reports	N/A	Required to initiate CLIN 0003
CLIN 0003	Preparation of the NDA	Successful completion of the NDA for FDA filing	Unable to complete the NDA for FDA filing	NDA data package	3.2.1	N/A
	Filing the NDA with the FDA	Successful approval of the NDA by the FDA	Rejection of the NDA by the FDA	NDA approval	3.2.2	N/A

* Certain confidential information contained in this document, marked [***], is filed separately with the Securities and Exchange Commission.

ATTACHMENT 4 – Invoice

INVOICE/FINANCING REQUEST AND CONTRACT FINANCIAL REPORTING INSTRUCTIONS FOR COST-REIMBURSEMENT TYPE CONTRACTS

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

Number of Copies: Payment requests shall be submitted in the quantity specified in the Invoice Submission Instructions in Section B of the Contract.

Frequency: Payment requests should not be submitted more frequently than once every two weeks in accordance with the Allowable Cost and Payment Clause incorporated into this contract unless otherwise instructed by the Contract Officer. Small business concerns may submit invoices/financing requests more frequently than every two weeks when authorized by the Contracting Officer.

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

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

Contractor's Fiscal Year: Payment requests shall be prepared in such a manner that the Government can identify costs claimed with the Contractor's fiscal year.

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

Costs Requiring Prior Approval: Costs requiring the Contracting Officer's approval, which are not set forth in an Advance Understanding in the contract, shall be identified and reference the Contracting Officer's Authorization (COA) Number. In addition, the Contractor shall show any cost set forth in an Advance Understanding as a separate line item on the payment request.

Invoice/Financing Request Identification: Each payment request shall be identified as either:

(a) **Interim Invoice/Contract Financing Request:** These are interim payment requests submitted during the contract performance period.

(b) **Completion Invoice:** The completion invoice shall be submitted promptly upon completion of the work, but no later than one year from the contract completion date, or within 120 days after settlement of the final indirect cost rates covering the year in which the contract is physically complete (whichever date is later). The Contractor shall submit the completion invoice when all costs have been assigned to the contract and it completes all performance provisions.

(c) **Final Invoice:** A final invoice may be required after the amounts owed have been settled between the Government and the Contractor (e.g., resolution of all suspensions and audit exceptions).

Preparation and Itemization of the Invoice/Financing Request: The Contractor shall furnish the information set forth in the instructions below. The instructions are keyed to the entries on the Sample Invoice/Financing Request.

(a) **Designated Billing Office Name and Address:** Enter the designated billing office name and address, as identified in the Invoice Submission Instructions in Section B and F of the Contract Schedule.

(b) **Contractor's Name, Address, Point of Contact, VIN, and DUNS or DUNS+4 Number:** Show the Contractor's name and address exactly as they appear in the contract, along with the name, title, phone number, and e-mail address of the person to notify in the event of an improper invoice or, in the case of payment by method other than Electronic Funds Transfer, to whom payment is to be sent. Provide the Contractor's Vendor Identification Number (VIN), and Data Universal Numbering System (DUNS) number or DUNS+4. The DUNS number must identify the Contractor's name and address exactly as stated on the face page of the contract. When an approved assignment has been made by the Contractor, or a different payee has been designated, provide the same information for the payee as is required for the Contractor (i.e., name, address, point of contact, VIN, and DUNS).

(c) **Invoice/Financing Request Number:** Insert the appropriate serial number of the payment request.

(d) **Date Invoice/Financing Request Prepared:** Insert the date the payment request is prepared.

(e) **Contract Number and Order Number (if applicable):** Insert the contract number and order number (if applicable).

(f) **Effective Date:** Insert the effective date of the contract or if billing under an order, the effective date of the order.

(g) **Total Estimated Cost of Contract/Order:** Insert the total estimated cost of the contract, exclusive of fixed-fee. If billing under an order, insert the total estimated cost of the order, exclusive of fixed-fee.

(h) **Total Fixed-Fee:** Insert the total fixed-fee (where applicable).

(i) **Two-Way/Three-Way Match:** Identify payment to be made using a three-way match.

(j) **Office of Acquisitions:** Insert the name of the Office of Acquisitions, as identified in Section G of the Contract Schedule.

(k) **Central Point of Distribution:** Insert the Central Point of Distribution, as identified in the Invoice Submission Instructions in Section G of the Contract Schedule.

(l) **Billing Period:** Insert the beginning and ending dates (month, day, and year) of the period in which costs were incurred and for which reimbursement is claimed.

(m) **Amount Billed - Current Period:** Insert the amount claimed for the current billing period by major cost element, including any adjustments and fixed-fee. If the Contract Schedule contains separately priced line items, identify the contract line item(s) on the payment request and include a separate breakdown (by major cost element) for each line item.

(n) **Amount Billed - Cumulative:** Insert the cumulative amounts claimed by major cost element, including any adjustments and fixed-fee. If the Contract Schedule contains separately priced line items, identify the contract line item(s) on the payment request and include a separate breakdown (by major cost element) for each line item.

(o) **Direct Costs:** Insert the major cost elements. For each element, consider the application of the paragraph entitled "Costs Requiring Prior Approval" on page 1 of these instructions.

(1)

(2) **Direct Labor:** Include salaries and wages paid (or accrued) for direct performance of the contract.

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

- hours or percentage of effort and cost by labor category (as specified in the Level of Effort Article in Section F of the contract) for the current billing period, and

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

(3) **Fringe Benefits:** List any fringe benefits applicable to direct labor and billed as a direct cost. Do not include in this category fringe benefits that are included in indirect costs.

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

* Certain confidential information contained in this document, marked [***], is filed separately with the Securities and Exchange Commission.

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

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

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

(5) **Materials and Supplies:** Include equipment with unit costs of less than $1,000 or an expected service life of two years or less, and consumable material and supplies regardless of amount.

(6) **Premium Pay:** List remuneration in excess of the basic hourly rate.

(7) **Consultant Fee:** List fees paid to consultants. Identify consultant by name or category as set forth in the contract or COA, as well as the effort (i.e., number of hours, days, etc.) and rate billed.

(8) **Travel:** Include domestic and foreign travel. Foreign travel is travel outside of Canada, the United States and its territories and possessions. However, for an organization located outside Canada, the United States and its territories and possessions, foreign travel means travel outside that country. Foreign travel must be billed separately from domestic travel.

(9) **Subcontract Costs:** List subcontractor(s) by name and amount billed. Cite applicable COA or notification.

(10) **Other:** List all other direct costs in total unless exceeding $1,000 in amount. If over $1,000, list cost elements and dollar amounts separately. If the contract contains restrictions on any cost element, that cost element must be listed separately.

(p) **Cost of Money (COM):** Cite the COM factor and base in effect during the time the cost was incurred and for which reimbursement is claimed.

(q) **Indirect Costs:** Identify the indirect cost base (IDC), indirect cost rate, and amount billed for each indirect cost category.

(r) **Fixed-Fee:** Cite the formula or method of computation for fixed-fee, if applicable. The fixed-fee must be claimed as provided for by the contract.

(s) **Total Amounts Claimed:** Insert the total amounts claimed for the current and cumulative periods.

(t) **Adjustments:** Include amounts conceded by the Contractor, outstanding suspensions, and/or disapprovals subject to appeal.

(u) **Grand Totals**

(v) **Certification of Salary Rate Limitation:** If required by the contract (see Invoice Submission Instructions in Section G of the Contract Schedule), the Contractor shall include the following certification at the bottom of the payment request:

"I hereby certify that the salaries billed in this payment request are in compliance with the Salary Rate Limitation Provisions in Section H of the contract."

(w) **Signature**

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

FINANCIAL REPORTING INSTRUCTIONS:

These instructions are keyed to the Columns on the sample invoice/financing request.

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

* Certain confidential information contained in this document, marked [***], is filed separately with the Securities and Exchange Commission.

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

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

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

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

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

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

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

Modifications: Any modification in the amount negotiated for an item since the preceding report should be listed in the appropriate cost category.

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

* Certain confidential information contained in this document, marked [***], is filed separately with the Securities and Exchange Commission.

SAMPLE INVOICE/FINANCING REQUEST AND CONTRACT FINANCIAL REPORT

(a)	Designated Billing Office Name and Address: DHHS/OS/ASPR/BARDA Attn: Contracting Officer 330 Independence Ave., S.W. Room G644 Washington, D.C. 20201	(c)	Invoice/Financing Request No.: Date Invoice Prepared: Contract No. and Order No. (if applicable): __
		(d)	
		(e)	Effective Date: Total Estimated Cost of Contract/Order: Total Fixed-Fee (if applicable): Two-Way Match: Three-Way Match:
(b)	Contractor's Name, Address, Point of Contact, VIN, and DUNS or DUNS+4 Number: ABC CORPORATION 100 Main Street Anywhere, USA Zip Code Name, Title, Phone Number, and E-mail Address of person to notify in the event of an improper invoice or, in the case of payment by method other than Electronic Funds Transfer, to whom payment is to be sent. **VIN:** **DUNS or DUNS+4:**	(f)	Office of Acquisitions: Central Point of Distribution:
		(g)	
		(h)	
		(i)	
		(j)	
		(k)	

(l) This invoice/financing request represents reimbursable costs for the period from__to

Expenditure Category* A	Cumulative Percentage of Effort/Hrs.		Amount Billed		Cost at Completion F	Contract Amount G	Variance H
	Negotiated B	Actual C	(m) Current D	(n) Cumulative E			
(o) Direct Costs:							
(1) Direct Labor							
(2) Fringe Benefits							
(3) Accountable Property							
(4) Materials & Supplies							
(5) Premium Pay							
(6) Consultant Fees							
(7) Travel							
(8) Subcontracts							
(9) Other							
Total Direct Costs							
(p) Cost of Money							
(q) Indirect Costs							
(r) Fixed Fee							
(s) Total Amount Claimed							
(t) Adjustments							
(u) Grand Totals							

I certify that all payments are for appropriate purposes and in accordance with the contract.

(Name of Official) (Title)

* Attach details as specified in the contract

* Certain confidential information contained in this document, marked [***], is filed separately with the Securities and Exchange Commission.