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

FORM 10-Q/A
(Amendment No. 1)

(Mark One)

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2014
or

☐ TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Commission File Number: 001-32587

PHARMATHENE, INC.

(Exact name of registrant as specified in its charter)

Delaware	**20-2726770**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
One Park Place, Suite 450, Annapolis, Maryland	**21401**
(Address of principal executive offices)	(Zip Code)

(410) 269-2600
(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data file required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large Accelerated Filer ☐	Accelerated Filer ☐
Non-Accelerated Filer x (Do not check if a smaller reporting company)	Smaller Reporting Company ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date: The number of shares of the registrant's Common Stock, par value $0.0001 per share, outstanding as of November 3, 2014 was 63,373,584.

EXPLANATORY NOTE

PharmAthene, Inc. (the "Company") is filing this Amendment No. 1 on Form 10-Q/A ("Amendment") to amend its Quarterly Report on Form 10-Q for the quarter ended September 30, 2014 (the "Form 10-Q"), which was originally filed with the Securities and Exchange Commission on November 6, 2014. The purpose of this Amendment is to refile Exhibit 10.61, which was originally filed with the Form 10-Q, without redaction in response to suggestions provided by the staff of the Securities and Exchange Commission relating to the confidential treatment request previously filed by the Company with respect to Exhibit 10.61.

This Amendment speaks as of the original filing date and does not reflect events occurring after the filing of the Form 10-Q or modify or update disclosures that may be affected by subsequent events. No revisions are being made to the Company's financial statements or any other disclosure contained in the Form 10-Q.

This Amendment is an exhibit-only filing. Except for the changes to Exhibit 10.61, this Amendment does not otherwise update any exhibits as originally filed or previously amended.

In addition, as required by Rule 12b-15 under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), new certifications by the Company's principal executive officer and principal financial officer are filed herewith as exhibits to this Amendment pursuant to Rule 13a-14(a) of the Exchange Act. The Company is not including certifications pursuant to Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. 1350) as no financial statements are being filed with this Amendment.

Item 6. Exhibits

No.	Description
10.61#	Contract with the National Institute of Allergy and Infectious Diseases of the National Institutes of Health for the Development of Vaccine Formulations Effective Against NIAID Priority Pathogens, dated September 9, 2014 (Contract No. HHSN272201400040C).
31.1#	Certification of Principal Executive Officer Pursuant to SEC Rule 13a-14(a)/15d-14(a)
31.2#	Certification of Principal Financial Officer Pursuant to SEC Rule 13a-14(a)/15d-14(a)
101.INS*	Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document

Filed herewith.

* Previously furnished with our Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2014, as filed on November 6, 2014.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused the report to be signed on its behalf by the undersigned, thereunto duly authorized.

PHARMATHENE, INC.

Dated: November 22, 2016

By: /s/ John M. Gill
Name: John M. Gill
Title: President and Chief Executive Officer

Dated: November 22, 2016

By: /s/ Philip MacNeill
Name: Philip MacNeill
Title: Vice President, Chief Financial Officer,
Treasurer and Secretary

Exhibit 10.61

OMB Approval 2700-0042

AWARD/CONTRACT	1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 350) ►	RATING N/A	PAGE OF PAGES 1 54
2. CONTRACT (Proc. Inst Ident.) NO. HHSN272201400040C	3. EFFECTIVE DATE September 10, 2014	4. REQUISITION/PURCHASE REQUEST/PROJECT NO. 3504714	

5. ISSUED BY	CODE	IO-NIAID	6. ADMINISTERED BY (*If other than Item 6*)	CODE	N/A
National Institutes of Health National Institute of Allergy and Infectious Diseases DEA, Office of Acquisitions 6700-B Rockledge Drive, Room 3108, MSC 7612 Bethesda, Maryland 20892-7612			MID RCB-B RFP-NIH-NIAID-DMID-AI2013174		

7 NAME AND ADDRESS OF CONTRACTOR (No. street, county, state and ZIP Code)	8. Delivery ☐ FOB ORIGIN x OTHER (*See below*) FOB Destination
PharmAthene, Inc. One Park Place, Suite 450 Annapolis, MD 21401	9. DISCOUNT FOR PROMPT PAYMENT N/A
	10. SUBMIT INVOICES ADDRESS SHOWN IN: ITEM Art. G.3.
CODE FACILITY CODE	

11. SHIP TO/MARK FOR Article F.2.	CODE N/A	12. PAYMENT WILL BE MADE BY See Article G.3.	CODE N/A
13. AUTHORITY FOR USING OTHER FULL AND OPEN COMPETITION: ☐ 10 U.S.C.2304(c) ( ) ☐ 41 U.S.C. 253(c)( )		14. ACCOUNTING AND APPROPRIATION DATA: SOCC 25.55	

15A. ITEM NO.	15B. SUPPLIES/SERVICES	15C. QUANTITY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT
Title: "Development of Vaccine Formulations Effective Against NIAID Priority Pathogens" Period: September 10, 2014 through January 5, 2016 Contract Type: Cost Plus Fixed Fee, Term with Options		FY 14	$5,206,725		
			15G. TOTAL AMOUNT OF CONTRACT ►		**$5,206,725**

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CONTRACTING OFFICER WILL COMPLETE ITEM 17 OR 18 AS APPLICABLE

17. ☒ CONTRACTOR'S NEGOTIATED AGREEMENT (*Contractor is required to sign this document and return __2__ 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. ☐ AWARD (Contractor is not required to sign this document) Your offer on Solicitation Number _____, including the additions or changes made by you which additions or changes are set forth in full above, is hereby accepted as 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 offer, and (b) this award/contract No further contractual document is necessary.
19A. NAME AND TITLE OF SIGNER (*Type or print*) Eric I. Richman, President & CEO	20A. NAME OF CONTRACTING OFFICER Michael C. Finn Contracting Officer, OA, DEA, NIAID, NIH, DHHS
19B. NAME OF CONTRACTOR _/s/ Eric I. Richman_ (*Signature of person authorized to sign*)	19C. DATE SIGNED 09/09/2014
20B. UNITED STATES OF AMERICA BY BY _/s/ Michael C. Finn_ (*Signature of Contracting Officer*)	20C. DATE SIGNED 09/09/2014

NSN 7540-01-152-8069
PREVIOUS EDITION UNUSABLE

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STANDARD FORM (REV. 4-85)
Prescribed by GSA
FAR (48 CFR) 53.214(a)

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PART I - THE SCHEDULE

SECTION A - SOLICITATION/CONTRACT FORM

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

The objective of this contract is to support the advanced development of candidate products, which consist of a vaccine component in combination with a dry formulation technology (also referred to as solid vaccine formulations), that increase duration of stability and minimize cold chain or preservative requirements. These products will likely be used to minimize the need for preservatives for in post-event settings following the intentional release of NIAID Category A, B and C Priority Pathogens or in response to naturally occurring outbreaks of infectious diseases caused by NIAID Category A, B and C Priority Pathogens.

ARTICLE B.2. ESTIMATED COST - OPTION

a. The estimated cost of the Base Period of this contract is $4,900,027.

b. The fixed fee for the Base Period of this contract is $306,698. The fixed fee shall be paid in installments based on fee payment schedule paragraph f. of this Article. Payment shall be subject to the withholding provisions of the clauses ALLOWABLE COST AND PAYMENT and FIXED FEE referenced in the General Clause Listing in Part II, ARTICLE I.1. of this contract.

c. The total estimated amount of the contract, represented by the sum of the estimated cost plus the fixed fee for the Base Period is $5,206,725.

d. If the Government exercises its option pursuant to the OPTION PROVISION Article in SECTION H of this contract, the Government's total estimated contract amount represented by the sum of the estimated cost plus the fixed fee will be increased as follows:

Base and Options Periods	Estimated Cost ($)	Fixed Fee ($)	Estimated Cost Plus Fixed Fee ($)
Base Period (exercised)	$ 4,900,027	$ 306,698	$ 5,206,725
Option Period 1	$ 2,117,028	$ 133,624	$ 2,250,652
Option Period 2	$ 2,527,646	$ 158,678	$ 2,686,324
Option Period 3	$ 1,059,604	$ 72,143	$ 1,131,747
Option Period 4	$ 2,594,450	$ 162,850	$ 2,757,300
Option Period 5	$ 1,780,811	$ 111,843	$ 1,892,654
Option Period 6	$ 954,408	$ 62,642	$ 1,017,050
Option Period 7	$ 4,003,922	$ 251,031	$ 4,254,953
Option Period 8	$ 6,524,831	$ 397,399	$ 6,922,230
Total (Base Period and Options)	**$ 26,462,727**	**$ 1,656,908**	**$ 28,119,635**

e. Payments will be made from the following PRISM/NBS Line Items as follows:

PRISM/NBS Line Item No.	Option/Increment Description	PRISM/NBS Line Item Period of Performance	Funded Amount
Line 1	Base Period	09/10/2014 - 01/05/2016	$ 5,206,725

f. Fee Payment Schedule Based on Contract Milestones:

The Contractor shall complete all work in accordance with the Statement of Work and the contract milestones set forth herein. The distribution of the fixed fee shall be paid in installments based on the COR's written certification regarding the completion of these milestones (Tasks) as follows:

Period of Performance	Task	Tasks Description	Deliverable	Fixed Fee
Base	1.1.1.1.1	rPA-V2 Tech Transfer - Approval of tech transfer package	Final tech transfer package	$ 76,675
Base	1.1.1.2	Developmental Material Production (rPA-V1) - Completion	Final summary of testing	$ 76,675
Base	1.1.1.1	Developmental Material Production (rPA-V2) - Completion	Final summary of testing	$ 76,675
Base	1.5.1.1.1	6-month Stability Data - Development Lots	Final 6-month time point stability report	$ 76,675
Option 1	1.5.1.1.2	12-month Stability Data - Development Lot (downselected product)	Development lot stability table update, including 12-month time point data	$ 133,624
Option 2	1.2.1.1.1.4	NZW Rabbit Immunogenicity & Efficacy Study - Protocol approved	Final study protocol	$ 39,670
Option 2	1.2.1.1.2	NZW Rabbit Immunogenicity & Efficacy Study - Completion of In-Life	Survival data (14 days post-challenge)	$ 39,670
Option 2	1.2.1.1.3	NZW Rabbit Immunogenicity & Efficacy Study - Report completion	Final study report	$ 39,670
Option 2	1.1.1.3	Process Development (Dual Chamber Syringe) - Completion	Final process development summary report	$ 39,670
Option 3	1.1.1.4.3	Engineering FDP Lot - Batch record finalized	Final batch record for engineering FDP lot	$ 36,072
Option 3	1.1.1.4.8	Engineering FDP Lot - Completion	Final certificate of testing for engineering FDP lot	$ 36,072
Option 4	1.5.1.2.1.3	3-month Stability Data - Engineering FDP lot	Engineering FDP lot stability table update, including 3-month time point data	$ 81,425
Option 4	1.5.1.2.1.5	6-month Stability Data - Engineering FDP lot	Engineering FDP lot stability table update, including 6-month time point data	$ 81,425
Option 5	1.1.1.5.2	cGMP FDP Lot - Batch record finalized	Final batch record for cGMP FDP lot	$ 55,922
Option 5	1.1.1.5	cGMP FDP Lot - Completion	Batch disposition documentation for cGMP FDP lot	$ 55,922
Option 6	1.2.2.1.1.5	GLP Repeated Dose Toxicology Study - Protocol approved	Final study protocol	$ 31,321

Period of Performance	Task	Tasks Description	Deliverable	Fixed Fee
Option 6	1.2.2.1.3	GLP Repeated Dose Toxicology Study - Report approved	Final study report	$ 31,321
Option 7	1.5.1.3.2.2	6-month Stability Data - cGMP FDP lot	cGMP FDP lot stability table update including 6-month time point data	$ 125,516
Option 7	1.5.1.3.2.6	12-month Stability Data - cGMP FDP lot	cGMP FDP lot stability table update including 12-month time point data	$ 125,516
Option 8	1.5.1.3.3.2	18-month Stability Data - cGMP FDP lot	cGMP FDP lot stability table update including 18-month time point data	$ 99,350
Option 8	1.3.1.1.1.6	Phase 1 Clinical Trial - Synopsis approved	Final study protocol synopsis	$ 99,350
Option 8	1.3.1.1.2	Phase 1 Clinical Trial - Execution complete (last patient visit)	Enrollment log reflecting final subject dosed in clinical trial	$ 99,350
Option 8	1.3.1.1.4	Phase 1 Clinical Trial - Final clinical study report approved	Final clinical study report	$ 99,350

ARTICLE B.3. ADVANCE UNDERSTANDINGS

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

a. **Subcontract**

1. To negotiate a subcontract agreement with Battelle for an amount not to exceed as follows:

   - Option 2: $746,556

   Award of the subcontract shall not proceed without the prior written consent of the Contracting Officer upon review of the supporting documentation required by FAR Clause 52.244-2, Subcontracts. After receiving written consent of the subcontract by the Contracting Officer, a copy of the signed, executed subcontract shall be provided to the Contracting Officer.

2. To negotiate a subcontract agreement with BPS-Baxter for an amount not to exceed as follows:

   - Base: $132,000
   - Option 1: $96,200
   - Option 3: $30,400
   - Option 4: $60,200
   - Option 5: $89,000
   - Option 7: $179,800
   - Option 8: $62,700

   Award of the subcontract shall not proceed without the prior written consent of the Contracting Officer upon review of the supporting documentation required by FAR Clause 52.244-2, Subcontracts. After receiving written consent of the subcontract by the Contracting Officer, a copy of the signed, executed subcontract shall be provided to the Contracting Officer.

3. To negotiate a subcontract agreement with BREL-BioReliance for an amount not to exceed as follows:

- Base: $93,325
- Option 1: $58,460
- Option 3: $17,066
- Option 4: $38,820
- Option 5: $31,996
- Option 7: $56,203
- Option 8: $22,236

Award of the subcontract shall not proceed without the prior written consent of the Contracting Officer upon review of the supporting documentation required by FAR Clause 52.244-2, Subcontracts. After receiving written consent of the subcontract by the Contracting Officer, a copy of the signed, executed subcontract shall be provided to the Contracting Officer.

4. To negotiate a subcontract agreement with Charles River Laboratories-PA for an amount not to exceed as follows:

- Option 6: $314,350

Award of the subcontract shall not proceed without the prior written consent of the Contracting Officer upon review of the supporting documentation required by FAR Clause 52.244-2, Subcontracts. After receiving written consent of the subcontract by the Contracting Officer, a copy of the signed, executed subcontract shall be provided to the Contracting Officer.

5. To negotiate a subcontract agreement with EPL Archives for an amount not to exceed as follows:

- Option 4: $1,272
- Option 7: $1,272
- Option 8: $1,590

Award of the subcontract shall not proceed without the prior written consent of the Contracting Officer upon review of the supporting documentation required by FAR Clause 52.244-2, Subcontracts. After receiving written consent of the subcontract by the Contracting Officer, a copy of the signed, executed subcontract shall be provided to the Contracting Officer.

6. To negotiate a subcontract agreement with FUJIFILM Diosynth Biotechnologies-US for an amount not to exceed as follows:

- Base: $111,584
- Option 1: $28,542
- Option 4: $71,892
- Option 7: $43,034
- Option 8: $14,042

Award of the subcontract shall not proceed without the prior written consent of the Contracting Officer upon review of the supporting documentation required by FAR Clause 52.244-2, Subcontracts. After receiving written consent of the subcontract by the Contracting Officer, a copy of the signed, executed subcontract shall be provided to the Contracting Officer.

7. To negotiate a subcontract agreement with INTERTEK for an amount not to exceed as follows:

- Base: $54,410
- Option 1: $19,300
- Option 3: $5,700
- Option 4: $34,645
- Option 5: $13,685
- Option 7: $45,905
- Option 8: $18,135

Award of the subcontract shall not proceed without the prior written consent of the Contracting Officer upon review of the supporting documentation required by FAR Clause 52.244-2, Subcontracts. After receiving written consent of the subcontract by the Contracting Officer, a copy of the signed, executed subcontract shall be provided to the Contracting Officer.

8. To negotiate a subcontract agreement with Lyo Tech for an amount not to exceed as follows:

- Base: $375,000
- Option 2: $251,600
- Option 3: $77,500
- Option 5: $164,700

Award of the subcontract shall not proceed without the prior written consent of the Contracting Officer upon review of the supporting documentation required by FAR Clause 52.244-2, Subcontracts. After receiving written consent of the subcontract by the Contracting Officer, a copy of the signed, executed subcontract shall be provided to the Contracting Officer.

9. To negotiate a subcontract agreement with Public Health England for an amount not to exceed as follows:

- Base: $956,468
- Option1: $496,467
- Option 3: $139,808
- Option 4: $735,993
- Option 5: $373,316
- Option 7: $1,107,004
- Option 8: $1,296,554

Award of the subcontract shall not proceed without the prior written consent of the Contracting Officer upon review of the supporting documentation required by FAR Clause 52.244-2, Subcontracts. After receiving written consent of the subcontract by the Contracting Officer, a copy of the signed, executed subcontract shall be provided to the Contracting Officer.

10. To negotiate a subcontract agreement with PPD Development for an amount not to exceed as follows:

- Base: $26,340
- Option 3: $7,205
- Option 5: $7,456

Award of the subcontract shall not proceed without the prior written consent of the Contracting Officer upon review of the supporting documentation required by FAR Clause 52.244-2, Subcontracts. After receiving written consent of the subcontract by the Contracting Officer, a copy of the signed, executed subcontract shall be provided to the Contracting Officer.

11. To negotiate a subcontract agreement with Quantics for an amount not to exceed as follows:

- Base: $32,725
- Option 1: $14,000
- Option 3: $8,834
- Option 4: $27,816
- Option 5: $18,996
- Option 7: $48,168
- Option 8: $19,448

Award of the subcontract shall not proceed without the prior written consent of the Contracting Officer upon review of the supporting documentation required by FAR Clause 52.244-2, Subcontracts. After receiving written consent of the subcontract by the Contracting Officer, a copy of the signed, executed subcontract shall be provided to the Contracting Officer.

12. To negotiate a subcontract agreement with Quintiles for an amount not to exceed as follows:

- Option 8: $1,359,429

Award of the subcontract shall not proceed without the prior written consent of the Contracting Officer upon review of the supporting documentation required by FAR Clause 52.244-2, Subcontracts. After receiving written consent of the subcontract by the Contracting Officer, a copy of the signed, executed subcontract shall be provided to the Contracting Officer.

13. To negotiate a subcontract agreement with Sharp for an amount not to exceed as follows:

- Base: $71,300
- Option 1: $71,700
- Option 4: $44,500
- Option 7: $72,500
- Option 8: $57,500

Award of the subcontract shall not proceed without the prior written consent of the Contracting Officer upon review of the supporting documentation required by FAR Clause 52.244-2, Subcontracts. After receiving written consent of the subcontract by the Contracting Officer, a copy of the signed, executed subcontract shall be provided to the Contracting Officer.

14. To negotiate a subcontract agreement with Stabilitech for an amount not to exceed as follows:

- Base: $89,044
- Option 1: $28,155

Award of the subcontract shall not proceed without the prior written consent of the Contracting Officer upon review of the supporting documentation required by FAR Clause 52.244-2, Subcontracts. After receiving written consent of the subcontract by the Contracting Officer, a copy of the signed, executed subcontract shall be provided to the Contracting Officer.

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

Name	Rate Per Hour	Number of Hours	Total Cost Including Travel Not to Exceed
Karie Hirst	*$165	456	$ 75,240

*PharmAthene has stated that the above individual is at or below the Salary Rate Limitation.

c. **Contract Number Designation**

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

Contract No. HHSN272201400040C.

d. **Advance Copies of Press Releases**

The contractor agrees to accurately and factually represent the work conducted under this contract in all press releases. In accordance with NIH Manual Chapter 1754, misrepresenting contract results or releasing information that is injurious to the integrity of NIH may be construed as improper conduct. The complete text of NIH Manual Chapter 1754 can be found at: http://www1.od.nih.gov/oma/manualchapters/management/1754/

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 Contracting Officer's Representative (COR) has received an advance copy of any press release related to this contract not less than four (4) working days prior to the issuance of the press release.

e. **Indirect Costs**

1. The Contractor may bill indirect costs at temporary billing rates as follows:

   Fringe Benefits = 36.21% of Direct Labor
   Overhead = 67.53% of Direct Labor and Fringe
   G&A = 45.38% of Total Costs including Direct Labor, Fringe, Overhead and allowable Other Direct Costs

These temporary rates may be utilized until such time as indirect cost rates have been established, provided, that the Contractor's indirect cost proposal is submitted to the cognizant office responsible for negotiating indirect costs no later than three (3) months after the effective date of this contract. If the indirect cost proposal is not submitted by that time, any temporary indirect costs billed after this due date will be suspended until such time as the indirect cost proposal is submitted.

2. The final amount reimbursable for indirect costs shall not exceed the following rates. Once indirect costs rates have been established, these ceilings may be renegotiated between the Contractor and the Contracting Officer and the ceilings lifted:

   Fringe Benefits = 36.21% of Direct Labor
   Overhead = 67.53% of Direct Labor and Fringe
   G&A = 45.38% of Total Costs including Direct Labor, Fringe, Overhead and allowable Other Direct Costs

The Government is not obligated to pay any additional amount should the negotiated indirect cost rates exceed these ceiling rates. In the event that the negotiated indirect cost rates are less than these ceilings rates, the Government's obligation should be reduced to conform to the lower rates.

ARTICLE B.4. PROVISIONS APPLICABLE TO DIRECT COSTS

a. **Items Unallowable Unless Otherwise Provided**

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

1. Conferences and Meetings

2. Food for Meals, Light Refreshments, and Beverages

3. Promotional Items *[includes, but is not limited to: clothing and commemorative items such as pens, mugs/cups, folders/folios, lanyards, and conference bags that are sometimes provided to visitors, employees, grantees, or conference attendees.]*

4. Acquisition, by purchase or lease, of any interest in real property;

5. Special rearrangement or alteration of facilities;

6. Purchase or lease of **any** item of general purpose office furniture or office equipment regardless of dollar value. (General purpose equipment is defined as any items of personal property which are usable for purposes other than research, such as office equipment and furnishings, pocket calculators, etc.);

7. Travel to attend general scientific meetings;

8. Foreign travel;

9. Consultant costs;

10. Subcontracts;

11. Patient care costs;

12. Accountable Government Property (defined as non-expendable personal property with an acquisition cost of $1,000 or more and "sensitive items" (defined as items of personal property (supplies and equipment that are highly desirable and easily converted to person use), regardless of acquisition value.

b. **Travel Costs**

1. Domestic Travel

   Total expenditures for domestic travel (transportation, lodging, subsistence, and incidental expenses) incurred in direct performance of this contract shall not exceed $50,120 without the prior written approval of the Contracting Officer.

2. The Contractor shall invoice and be reimbursed for all travel costs in accordance with Federal Acquisition Regulations (FAR) 31.2 - Contracts with Commercial Organizations, Subsection 31.205-46, Travel Costs.

SECTION C - STATEMENT OF WORK

ARTICLE C.1. STATEMENT OF WORK

a. 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 5, 2014, set forth in SECTION J-List of Attachments, attached hereto and made a part of this contract.

b. Privacy Act System of Records Number 09-25-0200 is applicable to this contract and shall be used in any design, development, or operation work to be performed under the resultant contract. Disposition of records shall be in accordance with SECTION C of the contract, and by direction of the Contracting Officer's Representative (COR).

ARTICLE C.2. REPORTING REQUIREMENTS

All reports required herein shall be submitted in electronic format. In addition, one hardcopy of each report shall be submitted to the Contracting Officer.

All electronic reports submitted shall be compliant with Section 508 of the Rehabilitation Act of 1973. Additional information about testing documents for Section 508 compliance, including guidance and specific checklists, by application, can be found at: http://www.hhs.gov/web/508/index.html under "Making Files Accessible."

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).

a. **Technical Reports**

In addition to those reports required by the other terms of this contract, the Contractor shall prepare and submit the following reports in the manner stated below and in accordance with the DELIVERIES Article in SECTION F of this contract:

[Note: Beginning May 25, 2008, the Contractor shall include, in any technical progress report submitted, the applicable PubMed Central (PMC) or NIH Manuscript Submission reference number when citing publications that arise from its NIH funded research.]

1. **Monthly Progress Report**

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

   The first report shall be due as set out in ARTICLE F.2.a. Thereafter, reports shall be due on or before the 15th Calendar day following each reporting period.

2. **Annual Progress Report**

This report shall include a summation of the results of the entire contract work for the period covered. An annual report will not be required for the period when the Final Report is due. A Monthly Report shall not be submitted when an Annual Report is due.

The first report shall cover the period September 10, 2014 through September 9, 2015 of this contract and shall be due on/before 30 days after the Anniversary Date of the Contract.

3. **Annual Technical Progress Report for Clinical Research Study Populations**

The Contractor shall submit information about the inclusion of women and members of minority groups and their subpopulations for each study being performed under this contract. The Contractor shall submit this information in the format indicated in the attachment entitled, "Cumulative Inclusion Enrollment Report," which is set forth in SECTION J of this contract. The Contractor also shall use this format, modified to indicate that it is a final report, for reporting purposes in the final report.

The Contractor shall submit the report in accordance with the DELIVERIES Article in SECTION F of this contract. In addition, the NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, Amended, October, 2001 applies. If this contract is for Phase III clinical trials, see II.B of these guidelines. The Guidelines may be found at the following website:

http://grants.nih.gov/grants/funding/women min/guidelines amended 10 2001.htm

Include a description of the plans to conduct analyses, as appropriate, by sex/gender and/or racial/ ethnic groups in the clinical trial protocol as approved by the IRB, and provide a description of the progress in the conduct of these analyses, as appropriate, in the annual progress report and the final report. If the analysis reveals no subset differences, a brief statement to that effect, indicating the subsets analyzed, will suffice. The Government strongly encourages inclusion of the results of subset analysis in all publication submissions. In the final report, the Contractor shall include all final analyses of the data on sex/gender and race/ethnicity.

4. **Final Report**

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

The Contractor shall provide the Contracting Officer with one electronic copy of the Final Report in draft form (in accordance with the DELIVERIES Article in SECTION F of this contract Calendar days prior to the expiration date of this contract.) The Contracting Officer's Representative (COR) will review the draft report and provide the Contracting Officer with comments within Calendar days after receipt. The Final Report shall be corrected by the Contractor, if necessary and the final version delivered as specified in the above paragraph.

5. **Summary of Salient Results**

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

6. **Reporting on Select Agents or Toxins and/or Highly Pathogenic Agents**

For work involving the possession, use, or transfer of a *Select Agent or Toxin and/or a Highly Pathogenic Agent*, the following information shall also be included in each Annual Progress Report:

1. Any changes in the use of the Select Agent or Toxin including initiation of "restricted experiments," and/or a Highly Pathogenic Agent, that have resulted in a change in the required biocontainment level, and any resultant change in location, if applicable, as determined by the IBC or equivalent body or institutional biosafety official.

2. If work with a new or additional *Select Agent or Toxin* and/or a Highly Pathogenic Agent will be conducted in the upcoming reporting period, provide:

    a. A list of each new or additional Select Agent or Toxin and/or a Highly Pathogenic Agent that will be studied;

    b. A brief description of the work that will be done with each new or additional Select Agent or Toxin and/or a Highly Pathogenic Agent and whether or not the work is a Select Agent or Toxin restricted experiment as defined in the Select Agents Regulation 42 CFR Part 73, Section 13.b (http://www.selectagents.gov/Regulations.html) or listed on the U.S. National Select Agents Registry restricted experiments website (http://www.selectagents.gov/Select%20Agents%20and%20Toxins%20Restricted%20Experiments.html);

    c. The name and location for each biocontainment resource/facility, including the name of the organization that operates the facility, and the biocontainment level at which the work will be conducted, with documentation of approval by your IBC or equivalent body or institutional biosafety official. It must be noted if the work is being done in a new location or different location.

    d. For work with Select Agents performed in the U.S. provide documentation of registration status of all domestic organizations where Select Agent(s) will be used. For work with Select Agents performed in a non-U.S. country prior NIAID approval is required.

If the IBC or equivalent body or institutional biosafety official has determined, for example, by conducting a risk assessment, that the work that has been performed or is planned to be performed under this contract may be conducted at a biocontainment safety level that is lower than BSL3, a statement to that affect shall be included in each Annual Progress Report.

If no work involving a Select Agent or Toxin and/or a Highly Pathogenic Agent has been performed or is planned to be performed under this contract, a statement to that affect shall be included in each Annual Progress Report.

b. **Other Reports/Deliverables**

1. **Information Security and Physical Access Reporting Requirements**

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

a. **Roster of Employees Requiring Suitability Investigations**

The Contractor shall submit a roster, by name, position, e-mail address, phone number and responsibility, of all staff (including subcontractor staff) working under the contract who will develop, have the ability to access, or host and/or maintain a Federal information system(s). The roster shall be submitted to the Contracting Officer's Representative (COR), with a copy to the Contracting Officer, within 14 calendar days of the effective date of the contract. (Reference subparagraph A.e. of the INFORMATION AND PHYSICAL ACCESS SECURITY Article in SECTION H of this contract.)

b. **IT Security Plan (IT-SP)**

In accordance with HHSAR Clause 352.239-72, Security Requirements For Federal Information Technology Resources, the contractor shall submit the IT-SP within thirty (30) days after contract award. The IT-SP shall be consistent with, and further detail the approach to, IT security contained in the Contractor's bid or proposal that resulted in the award of this contract. The IT-SP shall describe the processes and procedures that the Contractor will follow to ensure appropriate security of IT resources that are developed, processed, or used under this contract. If the IT-SP only applies to a portion of the contract, the Contractor shall specify those parts of the contract to which the IT-SP applies.

The Contractor shall review and update the IT-SP in accordance with NIST SP 800-53A, Guide for Assessing the Security Controls in Federal Information Systems and Organizations, on an annual basis.

(Reference subparagraph D.c.1. of the INFORMATION AND PHYSICAL ACCESS SECURITY Article in SECTION H of this contract.)

c. **IT Risk Assessment (IT-RA)**

In accordance with HHSAR Clause 352.239-72, Security Requirements For Federal Information Technology Resources, the contractor shall submit the IT-RA within thirty (30) days after contract award. The IT-RA shall be consistent, in form and content, with NIST SP 800-30, Risk Management Guide for Information Technology Systems, and any additions or augmentations described in the HHS-OCIO Information Systems Security and Privacy Policy.

The Contractor shall update the IT-RA on an annual basis.

(Reference subparagraph D.c.2. of the INFORMATION AND PHYSICAL ACCESS SECURITY Article in SECTION H of this contract.)

d. **FIPS 199 Assessment**

In accordance with HHSAR Clause 352.239-72, Security Requirements For Federal Information Technology Resources, the Contractor shall submit a FIPS 199 Assessment within thirty (30) days after contract award. The FIPS 199 Assessment shall be consistent with the cited NIST standard.

(Reference subparagraph D.c.3. of the INFORMATION AND PHYSICAL ACCESS SECURITY Article in SECTION H of this contract.

e. **IT Security Certification and Accreditation (IT-SC&A)**

In accordance with HHSAR Clause 352.239-72, Security Requirements For Federal Information Technology Resources, the Contractor shall submit written proof to the Contracting Officer that an IT-SC&A was performed within three (3) months after contract award.

The Contractor shall perform an annual security control assessment and provide to the Contracting Officer verification that the IT-SC&A remains valid.

(Reference subparagraph D.c.4. of the INFORMATION AND PHYSICAL ACCESS SECURITY Article in SECTION H of this contract.)

f. **Reporting of New and Departing Employees**

The Contractor shall notify the Contracting Officer's Representative (COR) and Contracting Officer within five working days of staffing changes for positions that require suitability determinations as follows:

a. **New Employees who have or will have access to HHS Information systems or data**: Provide the name, position title, e-mail address, and phone number of the new employee. Provide the name, position title and suitability level held by the former incumbent. If the employee is filling a new position, provide a description of the position and the Government will determine the appropriate security level.

b. **Departing Employees**: 1) Provide the name, position title, and security clearance level held by or pending for the individual; and 2) Perform and document the actions identified in the "Employee Separation Checklist", attached in Section J, ATTACHMENTS of this contract, when a Contractor/Subcontractor employee terminates work under this contract. All documentation shall be made available to the COR and/or Contracting Officer upon request.

(Reference subparagraph E.2.a-c. of the INFORMATION AND PHYSICAL ACCESS SECURITY Article in SECTION H of this contract.)

g. **Contractor - Employee Non-Disclosure Agreement(s)** The contractor shall complete and submit a signed and witnessed "Commitment to Protect Non-Public Information - Contractor Agreement" form for each contractor and subcontractor employee who may have access to non-public Department information under this contract. This form is located at: https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/ Nondisclosure.pdf.

(Reference subparagraph E.3.d. of the INFORMATION AND PHYSICAL ACCESS SECURITY Article in SECTION H of this contract.)

2. **Section 508 Annual Report**

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

ARTICLE C.3. INVENTION REPORTING REQUIREMENT

All reports and documentation required by FAR Clause 52.227-11, Patent Rights-Ownership by the Contractor including, but not limited to, the invention disclosure report, the confirmatory license, and the Government support certification, shall be directed to the Division of Extramural Inventions and Technology Resources (DEITR), OPERA, OER, NIH, 6705 Rockledge Drive, Suite 310, MSC 7980, Bethesda, Maryland 20892-7980 (Telephone: 301-435-1986). In addition, one copy of an annual utilization report, and a copy of the final invention statement, shall be submitted to the Contracting Officer. The final invention statement (see FAR 27.303(b)(2)(ii)) shall be submitted to the Contracting Officer on the expiration date of the contract.

The annual utilization report shall be submitted in accordance with the DELIVERIES Article in SECTION F of this contract. The final invention statement (see FAR 27.303(b)(2)(ii)) shall be submitted on the expiration date of the contract. All reports shall be sent to the following address:

Contracting Officer
National Institutes of Health
National Institute of Allergy and Infectious Diseases
DEA, Office of Acquisition
6700B Rockledge Drive, Room 3110
Bethesda, Maryland 20892- 7612

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

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

SECTION D - PACKAGING, MARKING AND SHIPPING

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

SECTION E - INSPECTION AND ACCEPTANCE

a. The Contracting Officer or the duly authorized representative will perform inspection and acceptance of materials and services to be provided.

b. For the purpose of this SECTION, The Contracting Officer's Representative is the authorized representative of the Contracting Officer.

c. Inspection and acceptance will be performed at:
National Institutes of Health
National Institute of Allergy and Infectious Diseases
Division of Microbiology and Infectious Diseases
5601 Fishers Lane, MSC 9825
Rockville, MD 20892-9825

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

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

FAR Clause **52.246-3, Inspection of Supplies - Cost-Reimbursement** (May 2001).

FAR Clause **52.246-8, Inspection of Research and Development - Cost-Reimbursement** (May 2001).

Alternate I (April 1984) is not applicable to this contract.

SECTION F - DELIVERIES OR PERFORMANCE

ARTICLE F.1. PERIOD OF PERFORMANCE

a. The period of performance of this contract shall be from September 10, 2014 through January 5, 2016.

b. If the Government exercises its option(s) pursuant to the OPTION PROVISION Article in Section H of this contract, the period of performance will be increased as listed below:

Option	Period of Performance
Base	September 10, 2014 to January 5, 2016
Option 1	*See note below.
Option 2	*See note below.
Option 3	*See note below.
Option 4	*See note below.
Option 5	*See note below.
Option 6	*See note below.
Option 7	*See note below.
Option 8	*See note below.

*Option is non-severable; therefore, the period of performance of the contract will extend by the period of time listed in the current GANTT Chart.

ARTICLE F.2. DELIVERIES

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

a. **Technical Progress Reports**

Item	Reports	Recipients	Delivery Schedule
1.	Monthly Progress Report (or Annual Progress Report)	1 electronic copy to COR and CO	The first report is due on/before November 15, 2014. Thereafter, each report is due on/before the 15th of the month following each reporting period. Monthly Progress Reports are not required when an Annual Progress Report, Draft Final Report or Final Report is due.
2.	Annual Technical Progress Report for Clinical Research Study Populations	1 electronic copy to COR, CO, and NIAID Regulatory Affairs Designee	The first report is due on/before November 15, 2015. Thereafter, each report is due on/before the 30th of the month following each anniversary date of the contract.

3.	DRAFT Final Report	1 electronic copy to COR and CO	A Draft Final Report shall be provided approximately 30 calendar days before the conclusion of each option period and shall cover all Milestones within that option. The option Periods are defined in the Additional options and related tasks table. COR's comments are due to the Contractor within 15 calendars days after receipt.
4.	Final Report and Summary of Salient Results	1 electronic copy to COR and CO	A Final Report shall be provided on/before the completion date of the conclusion of each option period and shall cover all tasks within that option. The option periods are defined in the Additional options and related tasks table.

b. **Other Reports and Deliverables (Delivery Schedule)**

Item	Deliverables	Recipient	Delivery Schedule
1.	Product Development Plan including Process/ Formulation, Assay, Non-Clinical/ Regulatory, Assay, and Device Development Plans (as applicable)	1 electronic copy to COR and CO	The initial plan is due 30 calendar days following the effective date of the contract. Updated plans annually on/before the 30th of the month following each anniversary date of the contract or as required by the COR prior to the initiation of major product development activities or as necessary in support of contract modifications.
2.	Quality Systems Agreements	1 electronic copy to COR	Within 30 calendar days of the effective date of contract/ subcontract award and prior to initiation of any major product development activities.
3.	All Development, Qualification and Validation Plans, Protocols, SOPs, and Reports	1 electronic copy to COR	Draft plans or protocols, as appropriate, 21 days prior to implementation. Draft reports within 60 days after completion of laboratory phase. Final reports within 7 days after incorporation of NIAID comments and release by QA.
4.	Draft and Final Batch Records for each production process	1 electronic copy to COR	Draft records 21 days prior to implementation. Final records within 7 days of lot disposition or release by QA.
5.	Certificates of Analysis for non cGMP and cGMP products	1 electronic copy to COR	Within 7 days of lot disposition or release by QA.
6.	Draft and Final Manufacturing Campaign Summary Report	1 electronic copy to COR	Within 7 days of release by QA.
7.	Stability Reports for non cGMP and cGMP product	1 electronic copy to COR	In accordance with FDA and ICH guidelines.

Item	Deliverables	Recipient	Delivery Schedule
8.	Animal, and other non-clinical study designs, protocols and reports:	1 electronic copy to COR and NIAID Regulatory Affairs Designee	Draft study designs and protocols for approval prior to ordering animals. Draft Protocols at least 21 days prior to protocol initiation. COR's comments are due to the Contractor within 14 calendars days after receipt. Final protocols 7 days prior to protocol initiation. Draft Unaudited Reports within 6 weeks of termination of the last animal on protocol, 12 weeks if full histopathology is required. Final reports within 7 days of incorporation of NIAID comments and release by QA.
9.	Chemistry, Manufacturing and Controls (CMC) information	1 electronic copy to COR and NIAID Regulatory Affairs Designee	At least 21 days prior to submission to FDA.
10.	Raw data and/or specific analyses of data generated by this contract	1 electronic copy to COR and NIAID Regulatory Affairs Designee	Within 30 calendar days of the request.
11.	Internal Audit Reports: As needed to evaluate compliance with FDA required cGMP, GLP and GCP standards	1 electronic copy to COR, CO, and NIAID Regulatory Affairs Designee	Within 30 calendar days of each audit.
12.	Audits by FDA involving contractor or subcontractor materials, facilities or operations related to this contract	1 Electronic copy to COR, CO, and NIAID Regulatory Affairs Designee	Notification within 7 calendar days of each audit. Reports within 7 calendar days of receipt of each audit from the FDA.
13.	FDA Pre IND Meeting Materials and Minutes	1 Electronic copy to COR and NIAID Regulatory Affairs Designee	-Pre IND Meeting materials. Within 21 calendar days prior to submission to FDA. COR's comments are due to the Contractor within 14 calendars days after receipt. -Pre IND Meeting Minutes. Within 7 calendar days after each meeting.
14.	Clinical Trial Protocols, Amendments, and Supporting Documents (draft, revisions and final)	1 Electronic copy to COR and NIAID Regulatory Affairs Designee	In accordance with to timelines or specified by DMID clinical operation guidelines.

Item	Deliverables	Recipient	Delivery Schedule
15.	FDA IND Submissions and Meeting Minutes	1 Electronic copy to COR and NIAID Regulatory Affairs Designee	-IND materials: At least 21 calendar days prior to submission to FDA. COR's comments are due to the Contractor within 14 calendars days after receipt. -IND Meeting minutes: Within 7 calendar days after each meeting.
16.	SAE Reports	1 Electronic copy to COR and NIAID Regulatory Affairs designee	In accordance with to timelines or specified by DMID clinical operation guidelines.
17.	FDA Correspondence and Meeting Summaries	1 Electronic copy to COR and NIAID Regulatory Affairs designee	-Within 5 business days after receipt from the FDA. -For correspondence to the FDA, within 5 business days prior to submission. -Meeting Minutes: Within 5 business days after each meeting.
18.	Draft and Final Clinical Study Reports	1 Electronic copy to COR and NIAID Regulatory Affairs designee	Draft Clinical Study Report shall be provided within ninety (90) calendar days of the completion of the analysis of all data generated in the clinical trial. Final Clinical Study Reports shall follow the ICH guidelines on Structure and Content of Clinical Study Reports E3
19.	Other clinical reports (for example, IND annual reports, NIH Clinical Population Reports, SMC Reports, Clinical Trial Monitoring Plan, Data Management Plan, Safety Oversight Plan, Quality Management Plan, and Clinical Monitoring Reports)	1 Electronic copy to COR	Submit according to timelines or specified by NIAID-DMID clinical operation guidelines.
20.	Contract Initiation Meeting, Annual Contract Review Meetings, and Additional Contract Meetings, Reports and Minutes.	1 electronic copy to COR and CO	Within 21 calendar days of each meeting.
21.	Publications and Presentations	1 electronic to COR	-For manuscripts, within 30 calendar days in advance of submission. COR's comments are due to the Contractor within 14 calendars days after receipt. -For abstracts and oral presentations, within 10 calendar days in advance of submission. COR's comments are due to the Contractor within 7 calendars days after receipt.

Item	Deliverables	Recipient	Delivery Schedule
22.	Annual Utilization Report	1 electronic to CO	Due on/before the 30th of the month following the anniversary date of the contract.
23.	Final Invention Statement	1 electronic to CO	Due on/before completion date of the contract.
24.	All reports and Documentation including the invention disclosure report, the confirmatory license, and the government support certification	1 electronic to OPERA	As required by FAR Clause 52.227-11.
25.	Technology Transfer	Technology Transfer packages that include complete protocols, assays or procedures developed and/or improved with contract funding.	To be decided as part of finalization of the SOW and other terms and conditions of any contract during negotiations.
26.	Institutional Biosafety Approval	Documentation (as applicable to subcontractors)	To be decided as part of finalization of the SOW and other terms and conditions of any contract during negotiations.
27.	Final Container Candidate Product	Delivery of 500 units of final container product to NIAID, and the necessary supporting documentation and letters of cross-reference.	As requested by the COR.

ARTICLE F.3. ARTICLE F.3. CLAUSES INCORPORATED BY REFERENCE, FAR 52.252-2 (FEBRUARY1998)

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

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:

52.242-15, Stop Work Order (August 1989)

Alternate I (April 1984) is applicable to this contract.

SECTION G - CONTRACT ADMINISTRATION DATA

ARTICLE G.1. CONTRACTING OFFICER'S REPRESENTATIVE (COR)

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

Sonia Shrivastava Gales
Contracting Officer's Representative (COR)
BVBPDS, OBRRTR
DMID/NIAID/NIH
galesso@niaid.nih.gov
Ph: 240-627-3251
Work cell: (301) 538-8571
5601 Fishers Lane, Room 8G48
North Bethesda, MD 20852
For FedEx/UPS use Rockville, MD 20852

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

The Contracting Officer is the only person with authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the statement of work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor for any costs incurred during the performance of this contract; (5) otherwise change any terms and conditions of this contract; or (6) sign written licensing agreements. Any signed agreement shall be incorporated by reference in Section K of the contract

The Government may unilaterally change its COR designation.

ARTICLE G.2. KEY PERSONNEL, HHSAR 352.242-70 (January 2006)

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

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

Name	Project Role
John Troyer, Ph.D.	Principal Investigator/Program Director
Robin Cameron	Program Manager
Sherry Crowe, Ph.D.	Director, Immunology/Non-clinical
Linda Maldonado, M.S.	Director, Process Sciences, Downstream
That Nguyen	Director, Quality
Bradford Powell, Ph.D.	Director, Analytical Sciences
TBH	Senior Clinical Trial Project Manager

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

a. Invoice Submission/Contract Financing Request and Contract Financial Reporting, NIH(RC)-4 for NIH Cost-Reimbursement Type Contracts are attached and made part of this contract. The Contractor shall follow the attached instructions and submission procedures specified below to meet the requirements of a "proper invoice" pursuant to FAR Subpart 32.9, Prompt Payment.

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

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

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

   b. One copy of the invoice shall be submitted to the **approving official via e-mail at**:

      NIAIDOAInvoices@niaid.nih.gov

      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. ***[Note: The original payment request must still be submitted in hard copy and mailed to the designated billing office to meet the requirements of a "proper invoice."]***

2. In addition to the requirements specified in FAR 32.905 for a proper invoice, the Contractor shall include the following information on the face page of all payment requests:

   a. Name of the Office of Acquisitions. The Office of Acquisitions for this contract is NIAID.

   b. Federal Taxpayer Identification Number (TIN). If the Contractor does not have a valid TIN, it shall identify the Vendor Identification Number (VIN) on the payment request. The VIN is the number that appears after the Contractor's name on the face page of the contract. *[Note: A VIN is assigned to new contracts awarded on or after June 4, 2007, and any existing contract modified to include the VIN number.]* If the Contractor has neither a TIN, DUNS, or VIN, contact the Contracting Officer.

   c. DUNS or DUNS+4 Number. The DUNS number must identify the Contractor's name and address exactly as stated in the contract and as registered in the Central Contractor Registration (CCR) database. If the Contractor does not have a valid DUNS number, it shall identify the Vendor Identification Number (VIN) on the payment request. The VIN is the number that appears after the Contractor's name on the face page of the contract. *[Note: A VIN is assigned to new contracts awarded on or after June 4, 2007, and any existing contract modified to include the VIN number.]* If the Contractor has neither a TIN, DUNS, or VIN, contact the Contracting Officer.

d. Invoice Matching Option. This contract requires a two-way match.

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

f. The Contract Title is:

Development of Vaccine Formulations Effective Against NIAID Priority Pathogens

g. PRISM/NBS Line Item Number and associated PRISM/NBS Line Item Period of Performance.

b. Inquiries regarding payment of invoices shall be directed to the designated billing office, (301) 496-6452.

c. The Contractor shall include the following certification on every invoice for reimbursable costs incurred with Fiscal Year funds subject to HHSAR Clause 352.231-70, Salary Rate Limitation in SECTION I of this contract. For billing purposes, certified invoices are required for the billing period during which the applicable Fiscal Year funds were initially charged through the final billing period utilizing the applicable Fiscal Year funds:

"I hereby certify that the salaries charged in this invoice are in compliance with HHSAR Clause 352.231-70, Salary Rate Limitation in SECTION I of the above referenced contract."

ARTICLE G.4. INDIRECT COST RATES

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

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

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

ARTICLE G.5. GOVERNMENT PROPERTY

a. In addition to the requirements of the clause, GOVERNMENT PROPERTY, incorporated in SECTION I of this contract, the Contractor shall comply with the provisions of HHS Publication, "HHS Contracting Guide for Contract of Government Property," which is incorporated into this contract by reference. This document can be accessed at:
http://www.hhs.gov/hhsmanuals/logisticsmanual/Appendix Q_HHS Contracting Guide.pdf.
Among other issues, this publication provides a summary of the Contractor's responsibilities regarding purchasing authorizations and inventory and reporting requirements under the contract.

Requests for information regarding property under this contract should be directed to the following office:

Division of Logistics Services, NIH
Property Management Branch
6011 Building, Suite 639
6011 EXECUTIVE BLVD MSC 7670
BETHESDA MD 20892-7670
nihcontractproperty@nih.gov

ARTICLE G.6. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

a. Contractor Performance Evaluations

Interim and Final evaluations of Contractor performance will be prepared on this contract in accordance with FAR Subpart 42.15. The Final performance evaluation will be prepared at the time of completion of work.

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

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

b. Electronic Access to Contractor Performance Evaluations

Contractors may access evaluations through a secure Web site for review and comment at the following address:

http://www.cpars.gov

SECTION H - SPECIAL CONTRACT REQUIREMENTS

ARTICLE H.1. PROTECTION OF HUMAN SUBJECTS, HHSAR 352.270-4(b) (January 2006)

a. The Contractor agrees that the rights and welfare of human subjects involved in research under this contract shall be protected in accordance with 45 CFR Part 46 and with the Contractor's current Assurance of Compliance on file with the Office for Human Research Protections (OHRP), Department of Health and Human Services. The Contractor further agrees to provide certification at least annually that the Institutional Review Board has reviewed and approved the procedures, which involve human subjects in accordance with 45 CFR Part 46 and the Assurance of Compliance.

b. The Contractor shall bear full responsibility for the performance of all work and services involving the use of human subjects under this contract and shall ensure that work is conducted in a proper manner and as safely as is feasible. The parties hereto agree that the Contractor retains the right to control and direct the performance of all work under this contract. The Contractor shall not deem anything in this contract to constitute the Contractor or any subcontractor, agent or employee of the Contractor, or any other person, organization, institution, or group of any kind whatsoever, as the agent or employee of the Government. The Contractor agrees that it has entered into this contract and will discharge its obligations, duties, and undertakings and the work pursuant thereto, whether requiring professional judgment or otherwise, as an independent contractor without imputing liability on the part of the Government for the acts of the Contractor or its employees.

c. If at any time during the performance of this contract, the Contracting Officer determines, in consultation with OHRP that the Contractor is not in compliance with any of the requirements and/or standards stated in paragraphs (a) and (b) above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. The Contracting Officer may communicate the notice of suspension by telephone with confirmation in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may, after consultation with OHRP, terminate this contract in whole or in part, and the Contractor's name may be removed from the list of those contractors with approved Human Subject Assurances.

(End of clause)

ARTICLE H.2. HUMAN SUBJECTS

Research involving human subjects shall not be conducted under this contract until the protocol developed in Phase I has been approved by NIAID, written notice of such approval has been provided by the Contracting Officer, and the Contractor has provided to the Contracting Officer a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310) certifying IRB review and approval of the protocol. The human subject certification can be met by submission of the Contractor's self designated form, **provided** that it contains the information required by the "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310).

When research involving Human Subjects will take place at collaborating sites or other performance sites, the Contractor shall obtain, and keep on file, a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310) certifying IRB review and approval of the research.

ARTICLE H.3. RESTRICTION ON USE OF HUMAN SUBJECTS, HHSAR 352.270-6 (January 2006)

Pursuant to 45 CFR part 46, Protection of Human Research Subjects, the Contractor shall not expend funds under this award for research involving human subjects or engage in any human subjects research activity prior to the Contracting Officer's receipt of a certification that the research has been reviewed and approved by the Institutional Review Board (IRB) designated under the Contractor's Federal-wide assurance of compliance. This restriction applies to all collaborating sites, whether domestic or foreign, and subcontractors. The Contractor must ensure compliance by collaborators and subcontractors.

(End of clause)

Prisoners shall not be enrolled in any HHS research activities until all requirements of HHS Regulations at 45 CFR PART 46, Subpart C have been met. If a Research Subject becomes a prisoner during the period of this contract, 45 CFR PART 46, Subpart C will apply to research involving that individual.

ARTICLE H.4. REQUIRED EDUCATION IN THE PROTECTION OF HUMAN RESEARCH PARTICIPANTS

NIH policy requires education on the protection of human subject participants for all investigators receiving NIH contract awards for research involving human subjects. For a complete description of the NIH Policy announcement on required education in the protection of human subject participants, the Contractor should access the NIH Guide for Grants and Contracts Announcement dated June 5, 2000 at the following website:

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html.

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

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

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

ARTICLE H.5. DATA AND SAFETY MONITORING IN CLINICAL TRIALS

The Contractor is directed to the full text of the NIH Policy regarding Data and Safety Monitoring and Reporting of Adverse Events, which may be found at the following web sites:

http://grants.nih.gov/grants/guide/notice-files/not98-084.html
http://grants.nih.gov/grants/guide/notice-files/not99-107.html
http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html

The Contractor must comply with the NIH Policy cited in these NIH Announcements and any other data and safety monitoring requirements found elsewhere in this contract.

Data and Safety Monitoring shall be performed in accordance with the approved Data and Safety Monitoring Plan.

The Data and Safety Monitoring Board shall be established and approved prior to beginning the conduct of the clinical trial.

ARTICLE H.6. REGISTRATION AND RESULTS REPORTING FOR APPLICABLE CLINICAL TRIALS IN CLINICALTRIALS.GOV

The Food and Drug Administration Amendments Act of 2007 (FDAAA) at: http://frwebgate.access.gpo.gov/cgi-bin/ getdoc.cgi?dbname=110_cong_public laws&docid=f:publ085.110.pdf, Title VIII, expands the National Institutes of Health's (NIH's) clinical trials registry and results database known as ClinicalTrials.gov and imposes new requirements that apply to specified "applicable clinical trials," including those supported in whole or in part by NIH funds. FDAAA requires:

- the registration of certain "applicable clinical trials" (see Definitions at: http://grants.nih.gov/ClinicalTrials_fdaaa/ definitions.htm) in ClinicalTrials.gov no later than 21 days after the first subject is enrolled; and

- the reporting of summary results information (including adverse events) no later than 1 year after the completion date (See Definitions at link above) for registered applicable clinical trials involving drugs that are approved under section 505 of the Food, Drug and Cosmetic Act (FDCA) or licensed under section 351 of the PHS Act, biologics, or of devices that are cleared under section 510k of FDCA.

In addition, the Contractor shall notify the Contracting Officer's Representative (COR), with the trial registration number (NCT number), once the registration is accomplished. This notification may be included in the Technical Progress Report covering the period in which registration occurred, or as a stand alone notification.

The IND Sponser will be determined after contract award. The IND Sponser will be considered the "Responsible Party" for the purposes of compliance with FDAAA which includes registration (and results reporting, if required) of applicable clinical trial(s) performed under this contract in the Government database, ClinicalTrials.gov (http:// www.ClinicalTrials.gov).

Additional information is available at: http://prsinfo.clinicaltrials.gov.

ARTICLE H.7. HUMAN MATERIALS

The acquisition and supply of all human specimen material (including fetal material) used under this contract shall be obtained by the Contractor in full compliance with applicable State and Local laws and the provisions of the Uniform Anatomical Gift Act in the United States, and no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

ARTICLE H.8. HUMAN MATERIALS (ASSURANCE OF OHRP COMPLIANCE)

The acquisition and supply of all human specimen material (including fetal material) used under this contract shall be obtained by the Contractor in full compliance with applicable State and Local laws and the provisions of the Uniform

Anatomical Gift Act in the United States, and no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

The Contractor shall provide written documentation that all human materials obtained as a result of research involving human subjects conducted under this contract, by collaborating sites, or by subcontractors identified under this contract, were obtained with prior approval by the Office for Human Research Protections (OHRP) of an Assurance to comply with the requirements of 45 CFR 46 to protect human research subjects. This restriction applies to all collaborating sites without OHRP-approved Assurances, whether domestic or foreign, and compliance must be ensured by the Contractor.

Provision by the Contractor to the Contracting Officer of a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310), certifying IRB review and approval of the protocol from which the human materials were obtained constitutes the written documentation required. The human subject certification can be met by submission of a self designated form, provided that it contains the information required by the "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310).

ARTICLE H.9. RESEARCH INVOLVING RECOMBINANT OR SYNTHETIC NUCLEIC ACID MOLECULES (Including Human Gene Transfer Research)

All research projects (both NIH-funded and non-NIH-funded) involving recombinant or synthetic nucleic acid molecules that are conducted at or sponsored by an entity in the U.S. that receives any support for recombinant or synthetic nucleic acid research from NIH shall be conducted in accordance with the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines) available at: http://oba.od.nih.gov/rdna/nih_guidelines_oba.html). All NIH-funded projects abroad that include recombinant or synthetic nucleic acid molecules must also comply with the *NIH Guidelines*.

The NIH Guidelines stipulate biosafety and containment measures for recombinant or synthetic nucleic acid research, which is defined in the NIH Guidelines as research with (1) molecules that a) are constructed by joining nucleic acid molecules and b) can replicate in a living cell, i.e. recombinant nucleic acids, or (2) nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, i.e. synthetic nucleic acids, or (3) molecules that result from the replication of those described in (1) or (2). The NIH Guidelines apply to both basic and clinical research. Specific guidance for the conduct of human gene transfer studies appears in Appendix M of the *NIH Guidelines*.

Failure to comply with the *NIH Guidelines* may result in suspension, limitation, or termination of the contract for any work related to recombinant or synthetic nucleic acid research or a requirement for the Contracting Officer to approve any or all recombinant or synthetic nucleic acid molecule projects under this contract. This includes the requirement for the institution to have an Institutional Biosafety Committee (IBC) registered with NIH OBA that complies with the requirements of the NIH Guidelines. Further information about compliance with the NIH Guidelines can be found on the NIH Office of Biotechnology Activities (OBA) website available at: http://oba.od.nih.gov/rdna_ibc/ibc.html.

ARTICLE H.10. NIH POLICY ON ENHANCING PUBLIC ACCESS TO ARCHIVED PUBLICATIONS RESULTING FROM NIH-FUNDED RESEARCH

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

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

ARTICLE H.11. 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.12. ACKNOWLEDGEMENT OF FEDERAL FUNDING

The Contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money: (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

ARTICLE H.13. RESTRICTION ON ABORTIONS

The Contractor shall not use contract funds for any abortion.

ARTICLE H.14. 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.15. 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.16. PRIVACY ACT, HHSAR 352.224-70 (January 2006)

This contract requires the Contractor to perform one or more of the following: (a) Design; (b) develop; or (c) operate a Federal agency system of records to accomplish an agency function in accordance with the Privacy Act of 1974 (Act) (5 U.S.C. 552a(m)(1)) and applicable agency regulations. The term "system of records" means a group of any records under the control of any agency from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual. Violations of the Act by the Contractor and/or its employees may result in the imposition of criminal penalties (5 U.S.C. 552a(i)). The Contractor shall ensure that each of its employees knows the prescribed rules of conduct and that each employee is aware that he/she is subject to criminal penalties for violation of the Act to the same extent as Department of Health and Human Services employees. These provisions also apply to all subcontracts the Contractor awards under this contract which require the design, development or operation of the designated system(s) of records [5 U.S.C. 552a(m)(1)]. The contract work statement: (a) identifies the system(s) of records and the design, development, or operation work the Contractor is to perform; and (b) specifies the disposition to be made of such records upon completion of contract performance.

(End of clause)

45 CFR Part 5b contains additional information which includes the rules of conduct and other Privacy Act requirements and can be found at: http://www.access.gpo.gov/nara/cfr/waisidx 06/45cfr5b 06.html.

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

ARTICLE H.17. CARE OF LIVE VERTEBRATE ANIMALS, HHSAR 352.270-5(b) (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; Web site: (http://www.aphis.usda.gov/animal_welfare).

(End of Clause)

ARTICLE H.18. 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 (PHS Policy). The PHS Policy can be accessed at: http:// grants1.nih.gov/grants/olaw/references/phspol.htm

In addition, the research involving live vertebrate animals shall be conducted in accordance with the description set forth in the Vertebrate Animal Section (VAS) of the contractor's technical proposal, as modified in the Final Proposal Revision (FPR), dated July 23, 2014, which is incorporated by reference.

ARTICLE H.19. PROTECTION OF PERSONNEL WHO WORK WITH NONHUMAN PRIMATES

All Contractor personnel who work with nonhuman primates or enter rooms or areas containing nonhuman primates shall comply with the procedures set forth in NIH Policy Manual 3044-2, entitled, "Protection of NIH Personnel Who Work with Nonhuman Primates," located at the following URL:

http://oma.od1.nih.gov/manualchapters/intramural/3044-2/

ARTICLE H.20. OMB CLEARANCE

In accordance with HHSAR 352.201-70, Paperwork Reduction Act, the Contractor shall not proceed with surveys or interviews until such time as Office of Management and Budget (OMB) Clearance for conducting interviews has been obtained by the Contracting Officer's Representative (COR) and the Contracting Officer has issued written approval to proceed.

ARTICLE H.21. RESTRICTION ON PORNOGRAPHY ON COMPUTER NETWORKS OMB CLEARANCE

The Contractor shall not use contract funds to maintain or establish a computer network unless such network blocks the viewing, downloading, and exchanging of pornography.

ARTICLE H.22. GUN CONTROL OMB CLEARANCE

The Contractor shall not use contract funds in whole or in part, to advocate or promote gun control.

ARTICLE H.23. CERTIFICATION OF FILING AND PAYMENT OF TAXES OMB CLEARANCE

The contractor must be in compliance with Section 518 of the Consolidated Appropriations Act of FY 2014.

ARTICLE H.24. OPTION PROVISION

Unless the Government exercises its option pursuant to the Option Clause set forth in SECTION I., the contract will consist only of the Base Period of the Statement of Work as defined in Sections C and F of the contract. Pursuant to FAR Clause 52.217-6, Option for Increased Quantity and FAR Clause 52.217-7, Option for Increased Quantity—Separately Priced Line Item, set forth in SECTION I. of this contract, the Government may, by unilateral contract modification, require the Contractor to perform additional options set forth in the Statement of Work and also defined in Sections C and F of the contract. If the Government exercises this option, notice must be given at least 60 days prior to the expiration date of this contract, and the estimated cost [plus fixed fee] of the contract will be increased as set forth in the ESTIMATED COST [PLUS FIXED FEE] Article in SECTION B of this contract.

ARTICLE H.25. INFORMATION AND PHYSICAL ACCESS SECURITY

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

a. **Applicability**. This clause applies whether the entire contract or order (hereafter "contract"), or portion thereof, includes information technology resources or services in which the Contractor has physical or logical (electronic) access to, or operates a Department of Health and Human Services (HHS) system containing, information that directly supports HHS' mission. The term "information technology (IT)", as used in this clause, includes computers, ancillary equipment (including imaging peripherals, input, output, and storage devices necessary for security and surveillance), peripheral equipment designed to be controlled by the central processing unit of a computer, software, firmware and similar procedures, services (including support services) and related resources. This clause does not apply to national security systems as defined in FISMA.

b. **Contractor responsibilities**. The Contractor is responsible for the following:

1. Protecting Federal information and Federal information systems in order to ensure their -

   a. Integrity, which means guarding against improper information modification or destruction, and includes ensuring information non-repudiation and authenticity;

   b. Confidentiality, which means preserving authorized restrictions on access and disclosure, including means for protecting personal privacy and proprietary information; and

   c. Availability, which means ensuring timely and reliable access to and use of information.

2. Providing security of any Contractor systems, and information contained therein, connected to an HHS network or operated by the Contractor, regardless of location, on behalf of HHS.

3. Adopting, and implementing, at a minimum, the policies, procedures, controls and standards of the HHS Information Security Program to ensure the integrity, confidentiality, and availability of Federal information and Federal information systems for which the Contractor is responsible under this contract or to which it may otherwise have access under this contract. The HHS Information Security Program is outlined in the HHS Information Security Program Policy, which is available on the HHS Office of the Chief Information Officer's (OCIO) Web site.

c. **Contractor security deliverables**. In accordance with the timeframes specified, the Contractor shall prepare and submit the following security documents to the Contracting Officer for review, comment, and acceptance:

1. **IT Security Plan (IT-SP)** - due within 30 days after contract award. The IT-SP shall be consistent with, and further detail the approach to, IT security contained in the Contractor's bid or proposal that resulted in the award of this contract. The IT-SP shall describe the processes and procedures that the Contractor will follow to ensure appropriate security of IT resources that are developed, processed, or used under this contract. If the IT-SP only applies to a portion of the contract, the Contractor shall specify those parts of the contract to which the IT-SP applies.

a. The Contractor's IT-SP shall comply with applicable Federal laws that include, but are not limited to, the Federal Information Security Management Act (FISMA) of 2002 (Title III of the E- Government Act of 2002, Public Law 107-347), and the following Federal and HHS policies and procedures:

   i. Office of Management and Budget (OMB) Circular A-130, Management of Federal Information Resources, Appendix III, Security of Federal Automation Information Resources.

   ii. National Institutes of Standards and Technology (NIST) Special Publication (SP) 800-18, Guide for Developing Security Plans for Information Systems, in form and content, and with any pertinent contract Statement of Work/Performance Work Statement (SOW/PWS) requirements. The IT-SP shall identify and document appropriate IT security controls consistent with the sensitivity of the information and the requirements of Federal Information Processing Standard (FIPS) 200, Recommend Security Controls for Federal Information Systems. The Contractor shall review and update the IT-SP in accordance with NIST SP 800-26, Security Self-Assessment Guide for Information Technology Systems and FIPS 200, on an annual basis.

   iii. HHS-OCIO Information Systems Security and Privacy Policy.

2. **IT Risk Assessment (IT-RA)** - due within 30 days after contract award. The IT-RA shall be consistent, in form and content, with NIST SP 800-30, Risk Management Guide for Information Technology Systems, and any additions or augmentations described in the HHS-OCIO Information Systems Security and Privacy Policy. After resolution of any comments provided by the Government on the draft IT-RA, the Contracting Officer shall accept the IT-RA and incorporate the Contractor's final version into the contract for Contractor implementation and maintenance. The Contractor shall update the IT-RA on an annual basis.

3. **FIPS 199 Standards for Security Categorization of Federal Information and Information Systems Assessment (FIPS 199 Assessment)** - due within 30 days after contract award. The FIPS 199 Assessment shall be consistent with the cited NIST standard. After resolution of any comments by the Government on the draft FIPS 199 Assessment, the Contracting Officer shall accept the FIPS 199 Assessment and incorporate the Contractor's final version into the contract.

4. **IT Security Certification and Accreditation (IT-SC&A)** - due within 3 months after contract award. The Contractor shall submit written proof to the Contracting Officer that an IT-SC&A was performed for applicable information systems - see paragraph (a) of this clause. The Contractor shall perform the IT-SC&A in accordance with the HHS Chief Information Security Officer's Certification and Accreditation Checklist; NIST SP 800-37, Guide for the Security, Certification and Accreditation of Federal Information Systems; and NIST 800-53, Recommended Security Controls for Federal Information Systems. An authorized senior management official shall sign the draft IT-SC&A and provided it to the Contracting Officer for review, comment, and acceptance.

a. After resolution of any comments provided by the Government on the draft IT SC&A, the Contracting Officer shall accept the IT-SC&A and incorporate the Contractor's final version into the contract as a compliance requirement.

b. The Contractor shall also perform an annual security control assessment and provide to the Contracting Officer verification that the IT-SC&A remains valid. Evidence of a valid system accreditation includes written results of:

i. Annual testing of the system contingency plan; and

ii. The performance of security control testing and evaluation.

d. **Personal identity verification**. The Contractor shall identify its employees with access to systems operated by the Contractor for HHS or connected to HHS systems and networks. The Contracting Officer's Representative (COR) shall identify, for those identified employees, position sensitivity levels that are commensurate with the responsibilities and risks associated with their assigned positions. The Contractor shall comply with the HSPD-12 requirements contained in "HHS-Controlled Facilities and Information Systems Security" requirements specified in the SOW/PWS of this contract.

e. **Contractor and subcontractor employee training**. The Contractor shall ensure that its employees, and those of its subcontractors, performing under this contract complete HHS-furnished initial and refresher security and privacy education and awareness training before being granted access to systems operated by the Contractor on behalf of HHS or access to HHS systems and networks. The Contractor shall provide documentation to the COR evidencing that Contractor employees have completed the required training.

f. **Government access for IT inspection**. The Contractor shall afford the Government access to the Contractor's and subcontractors' facilities, installations, operations, documentation, databases, and personnel used in performance of this contract to the extent required to carry out a program of IT inspection (to include vulnerability testing), investigation, and audit to safeguard against threats and hazards to the integrity, confidentiality, and availability, of HHS data or to the protection of information systems operated on behalf of HHS.

g. **Subcontracts**. The Contractor shall incorporate the substance of this clause in all subcontracts that require protection of Federal information and Federal information systems as described in paragraph (a) of this clause, including those subcontracts that -

a. Have physical or electronic access to HHS' computer systems, networks, or IT infrastructure; or

b. Use information systems to generate, store, process, or exchange data with HHS or on behalf of HHS, regardless of whether the data resides on a HHS or the Contractor's information system.

h. **Contractor employment notice**. The Contractor shall immediately notify the Contracting Officer when an employee either begins or terminates employment (or is no longer assigned to the HHS project under this contract), if that employee has, or had, access to HHS information systems or data.

i. **Document information**. The Contractor shall contact the Contracting Officer for any documents, information, or forms necessary to comply with the requirements of this clause.

j. **Contractor responsibilities upon physical completion of the contract**. The Contractor shall return all HHS information and IT resources provided to the Contractor during contract performance and certify that all HHS information has been purged from Contractor-owned systems used in contract performance.

k. **Failure to comply**. Failure on the part of the Contractor or its subcontractors to comply with the terms of this clause shall be grounds for the Contracting Officer to terminate this contract.

(End of Clause)

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

B. **Additional NIH Requirements**

1. **SECURITY CATEGORIZATION OF FEDERAL INFORMATION AND INFORMATION SYSTEMS (FIPS 199 Assessment)**

a. Information Type:

☐ Administrative, Management and Support Information:

☒ Mission Based Information:

b. Security Categories and Levels:

Confidentiality Level:	x Low	☐ Moderate	☐ High
Integrity Level:	☐ Low	x Moderate	☐ High
Availability Level:	x Low	☐ Moderate	☐ High
Overall Level:	☐ **Low**	x **Moderate**	☐ **High**

c. In accordance with HHSAR Clause 352.239-72, the contractor shall submit a FIPS 199 Assessment within 30 days after contract award. Any differences between the contractor's assessment and the information contained herein, will be resolved, and if required, the contract will be modified to incorporate the final FIPS 199 Assessment.

2. **INFORMATION SECURITY TRAINING**

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

a. Mandatory Training

i. All Contractor employees having access to (1) Federal information or a Federal information system or (2) sensitive data/information as defined at HHSAR 304.1300(a) (4), shall complete the NIH Computer Security Awareness Training course at http://irtsectraining.nih.gov/ before performing any work under this contract. Thereafter, Contractor employees having access to the information identified above shall complete an annual NIH-specified refresher course during the life of this contract. The Contractor shall also ensure subcontractor compliance with this training requirement.

ii. The Contractor shall maintain a listing by name and title of each Contractor/Subcontractor employee working on this contract and having access of the kind in paragraph 1.a(1) above, who has completed the NIH required training. Any additional security training completed by the Contractor/Subcontractor staff shall be included on this listing. The list shall be provided to the COR and/or Contracting Officer upon request.

b. Role-based Training

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

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

c. Rules of Behavior

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

3. **PERSONNEL SECURITY RESPONSIBILITIES**

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

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

b. **New contractor employees who have or will have access to HHS information systems or data**: The Contractor shall provide the COR with the name, position title, e-mail address, and phone number of all new contract employees working under the contract and provide the name, position title and position sensitivity level held by the former incumbent. If an employee is filling a new position, the Contractor shall provide a position description and the Government will determine the appropriate position sensitivity level.

c. **Departing contractor employees**: The Contractor shall provide the COR with the name, position title, and position sensitivity level held by or pending for departing employees. The Contractor shall perform and document the actions identified in the Contractor Employee Separation Checklist (https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/ Emp-sep-checklist.pdf) when a Contractor/subcontractor employee terminates work under this contract. All documentation shall be made available to the COR upon request.

d. **Commitment to Protect Non-Public Departmental Information and Data**.

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

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

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

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

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

NIH PII Spillage Report at: https://ocio.nih.gov/InfoSecurity/Policy/Documents/NIH_PII Spillage Proced.doc
NIH Lost or Stolen Assets Report at: https://ocio.nih.gov/InfoSecurity/Policy/Documents/ ISSO Stolen Device-Media Handling Procedures.doc

ARTICLE H.26. ELECTRONIC AND INFORMATION TECHNOLOGY ACCESSIBILITY, HHSAR 352.239-73(b) (January 2010)

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

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

c. In the event of a modification(s) to this contract/order, which adds new EIT products or services or revises the type of, or specifications for, products or services the Contractor is to provide, including EIT deliverables such as electronic documents and reports, the Contracting Officer may require that the contractor submit a completed HHS Section 508 Product Assessment Template to assist the Government in determining that the EIT products or services support Section 508 accessibility standards. Instructions for documenting accessibility via the HHS Section 508 Product Assessment Template may be found on the HHS Web site (http://www.hhs.gov/ web/508/contracting/technology/vendors.html).

[(End of HHSAR 352.239-73(b)]

d. Prior to the Contracting Officer exercising an option for a subsequent performance period/additional quantity or adding funding for a subsequent performance period under this contract, as applicable, the Contractor must provide a Section 508 Annual Report to the Contracting Officer and Project Officer. Unless otherwise directed by the Contracting Officer in writing, the Contractor shall provide the cited report in accordance with the following schedule. Instructions for completing the report are available in the Section 508 policy on the HHS Office on Disability Web site under the heading Vendor Information and Documents. The Contractor's failure to submit a timely and properly completed report may jeopardize the Contracting Officer's exercising an option or adding funding, as applicable.

Schedule for Contractor Submission of Section 508 Annual Report:

[End of HHSAR 352.239-73(c)]

ARTICLE H.27. INSTITUTIONAL RESPONSIBILITY REGARDING INVESTIGATOR FINANCIAL CONFLICTS OF INTEREST

The Institution (includes any contractor, public or private, excluding a Federal agency) 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 NIH 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. 45 CFR Part 94 is available at the following Web site: http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=0af84ca649a74846f102aaf664da1623&rgn=div5&view=text&node=45:1.0.1.1.51&idno=45. As required by 45 CFR Part 94, the Institution shall, at a minimum:

a. Maintain an up-to-date, written, enforceable policy on financial conflicts of interest that complies with 45 CFR Part 94, inform each Investigator of the policy, the Investigator's reporting responsibilities regarding disclosure of significant financial interests, and the applicable regulation, and make such policy available via a publicly accessible Web site, or if none currently exist, available to any requestor within five business days of a request. A significant financial interest means a financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

1. With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000. Included are payments and equity interests;

2. With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest; or

3. Intellectual property rights and interests, upon receipt of income related to such rights and interest.

Significant financial interests do not include the following:

1. Income from seminars, lectures, or teaching, and service on advisory or review panels for government agencies, Institutions of higher education, academic teaching hospitals, medical centers, or research institutes with an Institution of higher learning; and

2. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles.

b. Require each Investigator to complete training regarding the Institution's financial conflicts of interest policy prior to engaging in research related to any NIH-funded contract and at least every four years. The Institution must take reasonable steps [see Part 94.4(c)] to ensure that investigators working as collaborators, consultants or subcontractors comply with the regulations.

c. Designate an official(s) to solicit and review disclosures of significant financial interests from each Investigator who is planning to participate in, or is participating in, the NIH-funded research.

d. Require that each Investigator who is planning to participate in the NIH-funded research disclose to the Institution's designated official(s) the Investigator's significant financial interest (and those of the Investigator's spouse and dependent children) no later than the date of submission of the Institution's proposal for NIH- funded research. Require that each Investigator who is participating in the NIH-funded research to submit an updated disclosure of significant financial interests at least annually, in accordance with the specific time period prescribed by the Institution during the period of the award as well as within thirty days of discovering or acquiring a new significant financial interest.

e. Provide guidelines consistent with the regulations for the designated official(s) to determine whether an Investigator's significant financial interest is related to NIH-funded research and, if so related, whether the significant financial interest is a financial conflict of interest. An Investigator's significant financial interest is related to NIH-funded research when the Institution, thorough its designated official(s), reasonably determines that the significant financial interest: Could be affected by the NIH-funded research; or is in an entity whose financial interest could be affected by the research. A financial conflict of interest exists when the Institution, through its designated official(s), reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the NIH-funded research.

f. Take such actions as necessary to manage financial conflicts of interest, including any financial conflicts of a subcontractor Investigator. Management of an identified financial conflict of interest requires development and implementation of a management plan and, if necessary, a retrospective review and mitigation report pursuant to Part 94.5(a).

g. Provide initial and ongoing FCOI reports to the Contracting Officer pursuant to Part 94.5(b).

h. Maintain records relating to all Investigator disclosures of financial interests and the Institution's review of, and response to, such disclosures, and all actions under the Institution's policy or retrospective review, if applicable, for at least 3 years from the date of final payment or, where applicable, for the other time periods specified in 48 CFR Part 4, subpart 4.7, Contract Records Retention.

i. Establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator compliance as appropriate.

j. Complete the certification in Section K - Representations, Certifications, and Other Statements of Offerors titled "Certification of Institutional Policy on Financial Conflicts of Interest".

If the failure of an Institution 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 NIH-funded research, the Institution 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 Institution for further action, which may include directions to the Institution on how to maintain appropriate objectivity in the NIH- 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 Institution's review of, and response to, such disclosure, regardless of whether the disclosure resulted in the Institution'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 NIH-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 Part 94.6(b). The issuance of a Stop Work Order by the Contracting Officer may be necessary until the matter is resolved.

If the Contracting Officer determines that NIH-funded clinical research, whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, has been designed, conducted, or reported by an Investigator with a financial conflict of interest that was not managed or reported by the Institution, the Institution 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.28. PUBLICATION AND PUBLICITY

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, the Contractor shall acknowledge the support of the National Institutes of Health whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

> "This project has been funded in whole or in part with Federal funds from the National Institute of Alergy and Infectious Diseases, National Institutes of Health, Department of Health and Human Services, under Contract No. HHSN272201400040C"

ARTICLE H.29. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in NIH funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is **1-800-HHS-TIPS (1-800-447-8477)**. All telephone calls will be handled confidentially. The website to file a complaint on-line is: http://oig.hhs.gov/fraud/hotline/ and the mailing address is:

US Department of Health and Human Services
Office of Inspector General
ATTN: OIG HOTLINE OPERATIONS
P.O. Box 23489
Washington, D.C. 20026

ARTICLE H.30. YEAR 2000 COMPLIANCE

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

1. **Service Involving the Use of Information Technology**
YEAR 2000 COMPLIANCE—SERVICE INVOLVING THE USE OF INFORMATION TECHNOLOGY

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

(End of Clause)

ARTICLE H.31. OBTAINING AND DISSEMINATING BIOMEDICAL RESEARCH RESOURCES

Unique research resources arising from NIH-funded research are to be shared with the scientific research community. NIH provides guidance, entitled, "Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Final Notice," (Federal Register Notice, December 23, 1999 [64 FR 72090]), concerning the appropriate terms for disseminating and acquiring these research resources. This guidance, found at: http://www.gpo.gov/fdsys/pkg/FR-1999-12-23/pdf/99-33292.pdf is intended to help contractors ensure that the conditions they impose and accept on the transfer of research tools will facilitate further biomedical research, consistent with the requirements of the Bayh-Dole Act and NIH funding policy.

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

ARTICLE H.32. SHARING RESEARCH DATA

The Contractor's data sharing plan, dated July 16, 2014 is hereby incorporated by reference. The Contractor agrees to adhere to its plan and shall request prior approval of the Contracting Officer for any changes in its plan.

The NIH endorses the sharing of final research data to serve health. This contract is expected to generate research data that must be shared with the public and other researchers. NIH's data sharing policy may be found at the following Web site:

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html

NIH recognizes that data sharing may be complicated or limited, in some cases, by institutional policies, local IRB rules, as well as local, state and Federal laws and regulations, including the Privacy Rule (see HHS-published documentation on the Privacy Rule at http://www.hhs.gov/ocr/). The rights and privacy of people who participate in NIH-funded research must be protected at all times; thus, data intended for broader use should be free of identifiers that would permit linkages to individual research participants and variables that could lead to deductive disclosure of the identity of individual subjects.

ARTICLE H.33. POSSESSION USE AND TRANSFER OF SELECT BIOLOGICAL AGENTS OR TOXINS

The work being conducted under this contract may involve the possession, use, or transfer of a select agent or toxin. The contractor shall not conduct work involving a Select Agent or Toxin under this contract until it and any associated subcontractor(s) comply with the following:

For prime or subcontract awards to ***domestic institutions*** that possess, use, and/or transfer a Select Agent or Toxin under this contract, the institution must comply with the provisions of 42 CFR part 73, 7 CFR part 331, and/or 9 CFR part 121 (http://www.selectagents.gov/Regulations.html) as required, before using NIH funds for work involving a *Select Agent or Toxin*. **No NIH funds can be used for research involving a *Select Agent or Toxin* at a domestic institution without a valid registration certificate**.

For prime or subcontract awards to ***foreign institutions*** that possess, use, and/or transfer a *Select Agent or Toxin*, before using NIH funds for any work directly involving a *Select Agent or Toxin*, the foreign institution must provide information satisfactory to the NIAID that safety, security, and training standards equivalent to those described in 42 CFR part 73, 7 CFR part 331, and/or 9 CFR part 121 are in place and will be administered on behalf of all *Select Agent or Toxin* work supported by these funds. The process for making this determination includes a site visit to the foreign laboratory facility by an NIAID representative. During this visit, the foreign institution must provide the following information: concise summaries of safety, security, and training plans; names of individuals at the foreign institution who will have access to the Select Agent or Toxin and procedures for ensuring that only approved and appropriate individuals, in accordance with institution procedures, will have access to the Select Agents or Toxins under the contract; and copies of or links to any applicable laws, regulations, policies, and procedures applicable to that institution for the safe and secure possession, use, and/ or transfer of select agents. Site visits to foreign laboratories are conducted every three years after the initial review. **No NIH funds can be used for work involving a *Select Agent or Toxin* at a foreign institution without written approval from the Contracting Officer.**

Prior to conducting a restricted experiment with a Select Agent or Toxin under this contract or any associated subcontract, the contractor must discuss the experiment with the Contracting Officer's Representative (COR) and request and obtain written approval from the Contracting Officer. **Domestic institutions** must submit to the Contracting Officer written approval from the CDC to perform the proposed restricted experiment. **Foreign institutions** require review by a NIAID representative. The prime contractor must contact the COR and the NIAID Office of International Extramural Activities (OIEA) at mailto:niaidforeignawards@niaid.nih.gov for guidance on the process used by NIAID to review proposed restricted experiments. The NIAID website provides an overview of the review process at http://funding.niaid.nih.gov/researchfunding/sci/biod/pages/saconproc.aspx. The Contracting Officer will notify the prime contractor when the process is complete. **No NIH funds can be used for a restricted experiment with a Select Agent or Toxin at either a domestic or foreign institution without written approval from the Contracting Officer**.

Listings of HHS and USDA select agents and toxins, and overlap select agents or toxins as well as information about the registration process for domestic institutions, are available on the Select Agent Program Web site at http:// www.selectagents.gov/ and http://www.selectagents.gov/Select%20Agents%20and%20Toxins%20List.html.

For foreign institutions, see the NIAID Select Agent Award information: (http://funding.niaid.nih.gov/researchfunding/sci/biod/pages/default.aspx).

ARTICLE H.34. HIGHLY PATHOGENIC AGENTS

The work being conducted under this contract may involve a *Highly Pathogenic Agent (HPA)*. The NIAID defines an HPA as a pathogen that, under any circumstances, warrants a biocontainment safety level of BSL3 or higher according to either:

1. The current edition of the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL)(http:// www.cdc.gov/biosafety/publications/index.htm under "Publications");

2. The Contractor's Institutional Biosafety Committee (IBC) or equivalent body; or

3. The Contractor's appropriate designated institutional biosafety official.

If there is ambiguity in the BMBL guidelines and/or there is disagreement among the BMBL, an IBC or equivalent body, or institutional biosafety official, the highest recommended containment level must be used.

ARTICLE H.35. HOTEL AND MOTEL FIRE SAFETY ACT OF 1990 (P.L. 101-391)

Pursuant to Public Law 101-391, no Federal funds may be used to sponsor or fund in whole or in part a meeting, convention, conference or training seminar that is conducted in, or that otherwise uses the rooms, facilities, or services of a place of public accommodation that do not meet the requirements of the fire prevention and control guidelines as described in the Public Law. This restriction applies to public accommodations both foreign and domestic.

Public accommodations that meet the requirements can be accessed at: http://apps.usfa.fema.gov/hotel/.

ARTICLE H.36. 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.

ARTICLE H.37. USE OF FUNDS FOR CONFERENCES, MEETINGS AND FOOD

The Contractor shall not use contract funds (direct or indirect) to conduct meetings or conferences in performance of this contract without prior written Contracting Officer approval.

In addition, the use of contract funds to purchase food for meals, light refreshments, or beverages is expressly prohibited.

The following conferences and/or meetings have been approved by the Contracting Officer and are hereby authorized under this contract:

Conference or Meeting Title	Conference or Meeting Location	Federal/NonFederal Space	Date of Conference	Not to Exceed Estimate Cost
		[ ] Federal [ ] NonFederal		
		[ ] Federal [ ] NonFederal		
		[ ] Federal [ ] NonFederal		
		[ ] Federal [ ] NonFederal		

ARTICLE H.38. USE OF FUNDS FOR PROMOTIONAL ITEMS

The Contractor shall not use contract funds to purchase promotional items. Promotional items include, but are not limited to: clothing and commemorative items such as pens, mugs/cups, folders/folios, lanyards, and conference bags that are sometimes provided to visitors, employees, grantees, or conference attendees. This includes items or tokens given to individuals as these are considered personal gifts for which contract funds may not be expended.

PART II - CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

ARTICLE I.1. GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT

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 as follows: FAR Clauses at: http://www.acquisition.gov/far/. HHSAR Clauses at: http://www.hhs.gov/policies/hhsar/subpart352.html.

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

FAR CLAUSE NO.	***DATE***	***TITLE***
52.202-1	*Nov 2013*	*Definitions (Over the Simplified Acquisition Threshold)*
52.203-3	*Apr 1984*	*Gratuities (Over the Simplified Acquisition Threshold)*
52.203-5	*May 2014*	*Covenant Against Contingent Fees (Over the Simplified Acquisition Threshold)*
52.203-6	*Sep 2006*	*Restrictions on Subcontractor Sales to the Government (Over the Simplified Acquisition Threshold)*
52.203-7	*May 2014*	*Anti-Kickback Procedures (Over the Simplified Acquisition Threshold)*
52.203-8	*May 2014*	*Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Over the Simplified Acquisition Threshold)*
52.203-10	*May 2014*	*Price or Fee Adjustment for Illegal or Improper Activity (Over the Simplified Acquisition Threshold)*
52.203-12	*Oct 2010*	*Limitation on Payments to Influence Certain Federal Transactions (Over $150,000)*
52.203-17	*Apr 2014*	*Contractor Employee Whistleblower Rights and Requirements to Inform Employees of Whistleblower Rights (Over the Simplified Acquisition Threshold)*
52.204-4	*May 2011*	*Printed or Copied Double-Sided on Postconsumer Fiber Content Paper (Over the Simplified Acquisition Threshold)*
52.204-10	*Jul 2013*	*Reporting Executive Compensation and First-Tier Subcontract Awards ($25,000 or more)*
52.204-13	*Jul 2013*	*System for Award Management Maintenance*
52.209-6	*Aug 2013*	*Protecting the Government's Interest When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (Over $30,000)*
52.215-2	*Oct 2010*	*Audit and Records - Negotiation [Note: Applies to ALL contracts funded in whole or in part with Recovery Act funds, regardless of dollar value, AND contracts over the Simplified Acquisition Threshold funded exclusively with non-Recovery Act funds.]*
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 (Over $700,000)*
52.215-12	*Oct 2010*	*Subcontractor Cost or Pricing Data (Over $700,000)*
52.215-14	*Oct 2010*	*Integrity of Unit Prices (Over the Simplified Acquisition Threshold)*
52.215-15	*Oct 2010*	*Pension Adjustments and Asset Reversions (Over $700,000)*
52.215-18	*Jul 2005*	*Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) other than Pensions*

FAR CLAUSE NO.	*DATE*	*TITLE*
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 (Over the Simplified Acquisition Threshold)*
52.216-7	*Jun 2013*	*Allowable Cost and Payment*
52.216-8	*Jun 2011*	*Fixed Fee*
52.219-8	*May 2014*	*Utilization of Small Business Concerns (Over the Simplified Acquisition Threshold)*
52.219-9	*Jul 2013*	*Small Business Subcontracting Plan (Over $650,000, $1.5 million for Construction)*
52.219-16	*Jan 1999*	*Liquidated Damages - Subcontracting Plan (Over $650,000, $1.5 million for Construction)*
52.222-2	*Jul 1990*	*Payment for Overtime Premium (Over the Simplified Acquisition Threshold) (Note: The dollar amount in paragraph (a) of this clause is $0 unless otherwise specified in the contract.)*
52.222-3	*Jun 2003*	*Convict Labor*
52.222-21	*Feb 1999*	*Prohibition of Segregated Facilities*
52.222-26	*Mar 2007*	*Equal Opportunity*
52.222-35	*Jul 2014*	*Equal Opportunity for Veterans ($100,000 or more)*
52.222-36	*Jul 2014*	*Equal Opportunity for Workers with Disabilities*
52.222-37	*Jul 2014*	*Employment Reports on Veterans ($100,000 or more)*
52.222-40	*Dec 2010*	*Notification of Employee Rights Under the National Labor Relations Act (Over the Simplified Acquisition Threshold)*
52.222-50	*Feb 2009*	*Combating Trafficking in Persons*
52.222-54	*Aug 2013*	*Employment Eligibility Verification (Over the Simplified Acquisition Threshold)*
52.223-6	*May 2001*	*Drug-Free Workplace*
52.223-18	*Aug 2011*	*Encouraging Contractor Policies to Ban Text Messaging While Driving*
52.225-1	*May 2014*	*Buy American - Supplies*
52.225-13	*Jun 2008*	*Restrictions on Certain Foreign Purchases*
52.227-1	*Dec 2007*	*Authorization and Consent, Alternate I (Apr 1984)*
52.227-2	*Dec 2007*	*Notice and Assistance Regarding Patent and Copyright Infringement*
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*
52.232-9	*Apr 1984*	*Limitation on Withholding of Payments*
52.232-17	*May 2014*	*Interest (Over the Simplified Acquisition Threshold)*
52.232-20	*Apr 1984*	*Limitation of Cost*
52.232-23	*May 2014*	*Assignment of Claims*
52.232-25	*Jul 2013*	*Prompt Payment, Alternate I (Feb 2002)*
52.232-33	*Jul 2013*	*Payment by Electronic Funds Transfer—System for Award Management*
52.232-39	*Jun 2013*	*Unenforceability of Unauthorized Obligations*
52.233-1	*May 2014*	*Disputes*
52.233-3	*Aug 1996*	*Protest After Award, Alternate I (Jun 1985)*

FAR CLAUSE NO.	*DATE*	*TITLE*
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 (Over $700,000)*
52.242-4	*Jan 1997*	*Certification of Final Indirect Costs*
52.242-13	*Jul 1995*	*Bankruptcy (Over the Simplified Acquisition Threshold)*
52.243-2	*Aug 1987*	*Changes - Cost Reimbursement, Alternate V (Apr 1984)*
52.244-2	*Oct 2010*	*Subcontracts (Over the Simplified Acquisition Threshold), Alternate I (June 2007)*
52.244-5	*Dec 1996*	*Competition in Subcontracting (Over the Simplified Acquisition Threshold)*
52.244-6	*Jul 2014*	*Subcontracts for Commercial Items*
52.245-1	*Apr 2012*	*Government Property*
52.245-9	*Apr 2012*	*Use and Charges*
52.246-23	*Feb 1997*	*Limitation of Liability (Over the Simplified Acquisition Threshold)*
52.249-6	*May 2004*	*Termination (Cost-Reimbursement)*
52.249-14	*Apr 1984*	*Excusable Delays*
52.253-1	*Jan 1991*	*Computer Generated Forms*

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

HHSAR CLAUSE NO.	*DATE*	*TITLE*
352.202-1	*Jan 2006*	*Definitions - with Alternate paragraph (h) (Jan 2006)*
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*
352.227-70	*Jan 2006*	*Publications and Publicity*
352.228-7	*Dec 1991*	*Insurance - Liability to Third Persons*
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*

[End of GENERAL CLAUSES FOR A NEGOTIATED COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT- Rev. 08/2014].

ARTICLE 1.2. AUTHORIZED SUBSTITUTION OF CLAUSES

ARTICLE I.1. of this SECTION is hereby modified as follows:

a. **Alternate I**, (December 1991), of FAR Clause **52.233-1, Disputes** (December 1998) is added.

ARTICLE I.3. 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.

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

1. FAR Clause **52.203-13, Contractor Code of Business Ethics and Conduct** (April 2010).

2. FAR Clause **52.203-14, Display of Hotline Poster(s)** (December 2007).

"…..(3) Any required posters may be obtained as follows:

Poster(s)	**Obtain From"**
HHS Contractor Code of Ethics and Business Conduct Poster	http://oig.hhs.gov/fraud/report-fraud/OIG_Hotline_Poster.pdf

3. FAR Clause **52.215-17, Waiver of Facilities Capital Cost of Money** (October 1997).

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

"....The Contracting Officer may exercise the option by written notice to the Contractor within 60 days before the contract expires or prior to the exercise of the options...."

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

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

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

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

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

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

Additional purposes for which the limited rights data may be used are:

(i) Use (except for manufacture) by support service contract.
(ii) Evaluation by nongovernmental evaluators.
(iii) Use (except for manufacture) by other contractors participating in the Government's program of which the specific contract is a part

10. **Alternate V** (December 2007), FAR Clause **52.227-14, Rights in Data—General** (December 2007).

Specific data items that are not subject to paragraph (j) include: None

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

12. FAR Clause **52.227-17, Rights in Data—Special Works** (December 2007).

13. FAR Clause **52.230-2, Cost Accounting Standards** (May 2012).

14. FAR Clause **52.230-6, Administration of Cost Accounting Standards** (June 2010).

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

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

17. FAR Clause **52.247-68, Report of Shipment (REPSHIP)** (February 2006).

18. FAR Clause **52.251-1, Government Supply Sources** (April 2012).

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

1. HHSAR Clause **352.201-70, Paperwork Reduction Act** (January 2006).

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

3. HHSAR Clause **352.231-70, Salary Rate Limitation** (August 2012).

> **Note**: *P.L. 113-76 sets forth the Salary Rate Limitation at the Executive Level II Rate, effective January 17, 2014.*
>
> *See the following website for Executive Schedule rates of pay: http://www.opm.gov/oca/.*
>
> *(For current year rates, click on Salaries and Wages/Executive Schedule/Rates of Pay for the Executive Schedule. For prior year rates, click on Salaries and Wages/select Another Year at the top of the page/Executive Schedule/Rates of Pay for the Executive Schedule. Rates are effective January 1 of each calendar year unless otherwise noted.)*

4. HHSAR Clause **352.270-1, Accessibility of Meetings, Conferences and Seminars to Persons with Disabilities** (January 2001).

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

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

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

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

This contract incorporates the following clauses in full text.

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

1. *FAR Clause **52.209-9, Updates of Publicly Available Information Regarding Responsibility Matters** (July 2013)*

   As prescribed in 32.706-1(b), insert the following clause:

   a. *The Contractor shall update the information in the Federal Awardee Performance and Integrity Information System (FAPIIS) on a semi-annual basis, throughout the life of the contract, by posting the required information in the System for Award Management (SAM) database at http://www.acquisition.gov.*

   b. *As required by section 3010 of the Supplemental Appropriations Act, 2010 (Pub. L. 111-212), all information posted in FAPIIS on or after April 15, 2011, except past performance reviews, will be publicly available. FAPIIS consists of two segments—*

      1. The non-public segment, into which Government officials and the Contractor post information, which can only be viewed by—

         i. Government personnel and authorized users performing business on behalf of the Government; or

         ii. The Contractor, when viewing data on itself; and

      2. The publicly-available segment, to which all data in the non-public segment of FAPIIS is automatically transferred after a waiting period of 14 calendar days, except for—

         i. Past performance reviews required by subpart 42.15;

         ii. Information that was entered prior to April 15, 2011; or

         iii. Information that is withdrawn during the 14-calendar-day waiting period by the Government official who posted it in accordance with paragraph (c)(1) of this clause.

   c. *The Contractor will receive notification when the Government posts new information to the Contractor's record.*

      1. If the Contractor asserts in writing within 7 calendar days, to the Government official who posted the information, that some of the information posted to the non-public segment of FAPIIS is covered by a disclosure exemption under the Freedom of Information Act, the Government official who posted the information must within 7 calendar days remove the posting from FAPIIS and resolve the issue in accordance with agency Freedom of Information procedures, prior to reposting the releasable information. The contractor must cite 52.209-9 and request removal within 7 calendar days of the posting to FAPIIS.

      2. The Contractor will also have an opportunity to post comments regarding information that has been posted by the Government. The comments will be retained as long as the associated information is retained, i.e., for a total period of 6 years. Contractor comments will remain a part of the record unless the Contractor revises them.

3. *As required by section 3010 of Pub. L. 111-212, all information posted in FAPIIS on or after April 15, 2011, except past performance reviews, will be publicly available.*

d. *Public requests for system information posted prior to April 15, 2011, will be handled under Freedom of Information Act procedures, including, where appropriate, procedures promulgated under E.O. 12600.*

(End of clause)

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

NONE

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

The following documents are attached and incorporated in this contract:

1. Statement of Work

Statement of Work, dated September 5, 2014, 9 pages.

2. Invoice/Financing Request and Contract Financial Reporting Instructions for NIH Cost-Reimbursement Type Contracts, NIH(RC)-4

Invoice/Financing Request and Contract Financial Reporting Instructions for NIH Cost-Reimbursement Type Contracts, NIH(RC)-4, (8/12), 6 pages.

3. Cumulative Inclusion Enrollment Report

Cumulative Inclusion Enrollment Report, PHS 398/2590, (Rev. 08/12), 1 page. Located at:

http://grants.nih.gov/grants/funding/phs398/CumulativeInclusionEnrollmentReport.pdf

4. Privacy Act System of Records, Number

Privacy Act System of Records, Number 09-25-0200

5. Safety and Health

Safety and Health, HHSAR Clause 352.223-70, (1/06), 1 page.

6. Research Patient Care Costs

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

7. Disclosure of Lobbying Activities, SF-LLL

Disclosure of Lobbying Activities, SF-LLL, dated 7/97, 2 pages.

8. Roster of Employees Requiring Suitability Investigations

Roster of Employees Requiring Suitability Investigations, 1 page. Excel file located at:
https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/SuitabilityRoster_10-15-12.xlsx

9. Employee Separation Checklist

Employee Separation Checklist, 1 page. Fillable PDF format located at: https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/Emp-sep-checklist.pdf

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 are completed and located in The System for Award Management (SAM) website (http://www.sam.gov).

2. NIH Representations & Certifications, dated July 9, 2014

3. Human Subjects Assurance Identification Number FWA00010447.

    - Quintiles: IRB00001931: MidLands IRB #1
    - Quintiles: IRB00007629: MidLands IRB #2

4. Animal Welfare Assurance Number _____.

    - Battelle Memorial Institute A3034-01
    - Charles River Laboratories A3963-01
    - Public Health England A5560-01

END of the SCHEDULE

(CONTRACT)

STATEMENT OF WORK

1.1 Research and Technical Objectives

The research and technical objectives of this proposal are:

1. To assess two unique approaches to heat stabilize an rPA/Alhydrogel vaccine and downselect to one approach based on thermal stability and immunopotency data

    a. rPA-V1: rPA/Alhydrogel stabilized and freeze dried together

    b. rPA-V2: rPA stabilized for freeze drying separate from Alhydrogel and the Alhydrogel formulated in a buffer system suitable for use as reconstitution solution

2. To develop an innovative delivery platform (dual-chamber syringe) and produce engineering lot material for use in preclinical studies

3. To compare efficacy and immunogenicity of the lyophilized vaccine candidate to the currently licensed anthrax vaccine, AVA, in NZW rabbits

4. To determine that the selected heat stabilized dual chamber syringe product candidate is safe in a repeated-dose rat toxicology study

5. To produce cGMP heat stabilized dual chamber syringe final drug product for non-clinical and clinical testing

6. To confirm that the selected heat stabilized dual chamber syringe final drug product is safe and well-tolerated in humans in a Phase 1 clinical trial

1.2 Technical Approach and Method

We believe that the technical and delivery platform to be utilized in this proposal will result in a heat stable, single unit dose anthrax vaccine that significantly improves the ease and accuracy of delivery and simplifies the logistics of transporting and stockpiling the product.

This section describes the proposed technical plan and approach that has been devised to deliver the overall project goals to develop the vaccine up to and including a Phase 1 clinical trial. The planned approach contains a series of decision points at which a go/no go/redirect assessment can be made within the plan prior to moving forward with additional development activities.

- **Demonstration and Development Manufacturing of rPA-V1 and rPA-V2**. Development lots of both vaccine candidates will be manufactured using cGMP BDS produced under BARDA contract #HHSO1002900103C and assessed for thermal stability and immunopotency using established stability indicating assays. A downselect to a single product candidate will occur based on 6 month stability data obtained from the developmental manufacturing material.

- **Process Development, Engineering Manufacturing, and NZW Rabbit Immunogenicity and Efficacy Study**. The selected approach will move forward into process development in the dual-chambered syringe, followed by non-cGMP engineering lot manufacture and stability testing. For NIAID programmatic purposes, a standard vaccine immunogenicity study followed by aerosol spore challenge in the NZW rabbit has been planned to compare the selected lyophilized vaccine candidate with the currently licensed anthrax vaccine, AVA. A Pre-IND meeting will also be held with FDA to gain concurrence for the preclinical and clinical plan. Survival and TNA data from the NZW rabbit study indicating that the lyophilized vaccine candidate is at least equivalent to the response following AVA immunization and successful completion of engineering lot testing and release would allow the program to proceed to cGMP manufacturing and the planned GLP toxicology study.

- **cGMP Manufacturing and IND-enabling Toxicology Testing**. A clinical lot of cGMP FDP will be manufactured using cGMP BDS produced under BARDA contract #HHSO1002900103C and placed on stability for the planned Phase 1 clinical study. Engineering lot FDP will be used to initiate and complete a rodent pre-clinical toxicology study. The successful release of the cGMP clinical lot as well as successful completion and final report of the toxicology study will allow PharmAthene to initiate the Phase 1 clinical trial.

- **Phase 1 Clinical Trial**. A small Phase 1 clinical trial will be performed following the successful IND submission to assess the safety, tolerability and immunogenicity of the dual-chambered vaccine compared to AVA. There is no decision point associated with the option as it concludes the program; however, the objective is to demonstrate successful clinical proof-of-concept results for the candidate vaccine for future development.

Table 1 provides a summary of the proposed development activities by funding period (base/options).

Table 1: Summary of Proposed Development Activities

WBS	Activity
Base	**Developmental Manufacturing and Supportive Activities GFY15**
1.1.1.1	Developmental Material Production (rPA-V2)
1.1.1.2	Developmental Material Production (rPA-V1)
1.5.1.1.1	Stability- Development Lots- GFY15
1.5.1.4.1	Stability- BDS cGMP Lot- GFY15
1.5.2.1	Storage (Product)- GFY15
1.5.3.1	Reference Standard/Critical Reagent Management- GFY15
1.6.1.1	Project Initiation/Kick-off
Option 1	**Supportive Activities GFY16**
1.5.1.1.2	Stability- Development Lots- GFY16
1.5.1.4.2	Stability- BDS cGMP Lot- GFY16
1.5.2.2	Storage (Product)- GFY16
1.5.3.2	Reference Standard/Critical Reagent Management- GFY16
Option 2	**Process Development & NZW Rabbit Immunogenicity & Efficacy Study**
1.1.1.3	Process Development (Dual-chamber Syringe)
1.2.1.1	NZW Rabbit Immunogenicity & Efficacy Study
1.4.1.1	Pre-IND Meeting
Option 3	**Engineering FDP Lot Manufacture**
1.1.1.4	Engineering FDP Lot (Selected Product; Dual-chamber Syringe)
Option 4	**Supportive Activities GFY17**
1.5.1.2.1	Stability- Engineering FDP Lot (Lyo rPA)- GFY17

WBS	Activity
1.5.1.4.3	Stability- BDS cGMP Lot- GFY17
1.5.2.3	Storage (Product)- GFY17
1.5.3.3	Reference Standard/Critical Reagent Management- GFY17
1.5.4.1	Storage (Non-clinical/Clinical Sample)- GFY17
Option 5	**cGMP FDP Lot Manufacture and Supporting Stability GFY17**
1.1.1.5	cGMP FDP Lot (Selected Product; Dual-chamber Syringe)
1.5.1.3.1	Stability- cGMP FDP Lot (Lyo rPA)- GFY17
Option 6	**IND-enabling Toxicology Study**
1.2.2.1	GLP Repeated-dose Toxicology Study (Rat)
1.4.1.2	IND Submission
Option 7	**Supportive Activities GFY18**
1.5.1.2.2	Stability- Engineering FDP Lot (Lyo rPA)- GFY18
1.5.1.3.2	Stability- cGMP FDP Lot (Lyo rPA) -GFY18
1.5.1.4.4	Stability- BDS cGMP Lot- GFY18
1.5.2.4	Storage (Product)- GFY18
1.5.3.4	Reference Standard/Critical Reagent Management- GFY18
1.5.4.2	Storage (Non-clinical/Clinical Samples)- GFY18
Option 8	**Clinical Assessment & Supportive Activities GFY19-20**
1.3.1.1	Phase I Safety & Immunogenicity Clinical Trial
1.5.1.2.3	Stability- Engineering FDP Lot (Lyo rPA)- GFY19
1.5.1.3.3	Stability- cGMP FDP Lot (Lyo rPA)- GFY19
1.5.2.5	Storage (Product)- GFY19-20
1.5.3.5	Reference Standard/Critical Reagent Management- GFY19
1.5.4.3	Storage (Non-clinical/Clinical Sample)- GFY19-20

1.3 Candidate Product Overview Table

Table 2 contains an overview of the program activities by the proposed Base and Option.

Table 2: Candidate Product Overview Table

WBS/Task	Description	Go/No Go Criteria	Deliverable
BASE: Developmental Manufacturing and Supportive Activities GFY15			
1.6.1.1: Project Kick-off/Start-up	Internal project initiation, set-up and kick-off meetings	N/A	Draft & final product development plan (PDP) including process/formulation development, device development, non-clinical, assay development, and clinical/regulatory plans, draft & final statement of work (SOW), meeting agendas, presentations & minutes, completed SOPs, quality agreements & subcontractor audit reports
1.1.1.1: Developmental Material Production (rPA-V2)	Material produced will be placed on stability to inform a downselect to one product; material will be used to perform process development on selected product	**Go**: Lyophilization complete and with acceptable analytical quality · The time 0 stability data will be assessed. · The critical assays include iCE for deamidation and the IPA for immunopotency **No-Go**: Lyophilization not successful - Redirect to rPA-V1; a failure of the product in the IPA would eliminate the product from further consideration	Draft & final tech transfer package, draft & final batch summary report, draft & final sterilization validation protocol, draft & final sterilization validation report, draft & final summary of testing (SoT) at completion of production, draft & final development summary report (rPA-V1/V2), draft & final audit reports (as applicable)

WBS/Task	Description	Go/No Go Criteria	Deliverable
1.1.1.2: Developmental Material Production (rPA-V1)	Material produced will be placed on stability to inform a downselect to one product; material will be used to perform process development on selected product	**Go**: Lyophilization complete and with acceptable analytical quality · The time 0 stability data will be assessed. · The critical assays include iCE for deamidation and the IPA for immunopotency **No-Go**: Lyophilization not successful - Redirect to rPA-V2; A failure of the product in the IPA would eliminate the product from further consideration	Draft & final batch summary report, draft & final summary of testing (SoT) at completion of production, draft & final development summary report (rPA-V1/V2), draft & final audit reports (as applicable)
1.5.1.1.1: Stability-Development Lots GFY15	12 month stability program for developmental lots of rPA-V2 and rPA-V1. The 3-month and 6-month time points will occur in GFY15. The 6-month time point will be used to inform the downselect.	**Go**: 6-month stability data will trigger a down-select to one product approach. Critical assays include iCE for deamidation and the IPA for immunopotency. The stability data, both physical/chemical and IPA will be evaluated and compared to determine the performance of the product as stored at all temperatures. The down selection of rPA-V1 versus rPA-V2 will be a data driven approach based upon stability data, physical/chemical data, projected stability profiles and a detailed cost analysis.	Draft & final development lot stability protocol, draft & final development lot(s) stability table updates, draft & final 6-month stability report, draft & final audit reports (as applicable)
1.5.1.4.1: Stability-BDS cGMP Lot-GFY15	Ongoing stability testing of the cGMP rPA BDS	**Go**: Product remains within analytical specifications **No-Go/Redirect**: The stability at -70°C fails. A new lot of BDS will be manufactured	Draft & final GMP BDS lot stability table updates, draft & final audit reports (as applicable)
1.5.2.1: Storage (Product) - GFY15	Storage of development product	N/A	Draft & final audit reports (as applicable)

WBS/Task	Description	Go/No Go Criteria	Deliverable
1.5.3.1: Ref Std/Critical Reagent Mgmt - GFY15	· Requalification for two reference standards (lots B2272-007 and 11MF4907001-RS001) · rLF Requalification · IPA Diluent Requalification	**Go**: Standards or critical reagents remain within analytical specifications **No-Go/Redirect**: Requalification fails. A new standard or critical reagent will be manufactured/qualified	Draft & final reference standard testing protocol, draft & final reference standard qualification certificates, draft & final qualification reports, draft & final audit reports (as applicable)
OPTION 1: Supportive Activities GFY16			
1.5.1.1.2: Stability-Development Lots GFY16	Completion of the 12 month stability program for developmental lots of rPA-V2 and rPA-V1 initiated in GFY15. The 6 month time point was used to inform the downselect. The 12 month stability data will inform if further development is needed or continue with engineering lot	**Go**: Lyophilized Product remains within analytical specifications. Product demonstrates enhanced stability as compared to existing liquid stability data up to 12 months at 2-8°C and six months (analytical assay) and three months (potency) at 25°C by iCE, LDS-PAGE and IPA. **No-Go/Redirect**: The stability at 2-8°C or 25°C fails. Additional development studies required	Draft & final development lot(s) stability table updates, draft & final audit reports (as applicable)
1.5.1.4.2: Stability-BDS cGMP Lot-GFY16	Ongoing stability testing of the cGMP rPA BDS	**Go**: Product remains within analytical specifications **No Go/Redirect**: The stability at -70°C fails. A new lot of BDS will be manufactured	Draft & final GMP BDS lot stability table updates, draft & final audit reports (as applicable)
1.5.2.2: Storage (Product) - GFY16	Storage of development and engineering product	N/A	Draft & final audit reports (as applicable)
1.5.3.2: Ref Std/Critical Reagent Mgmt - GFY16	· Reference Standard Requalification (lot 11MF4907001-RS001) · rLF Requalification · IPA Diluent Requalification	**Go**: Standards or critical reagents remain within analytical specifications **No Go/Redirect**: Requalification fails. A new standard or critical reagent will be manufactured/qualified	Draft & final qualification reports, draft & final reference standard qualification certificates, draft & final audit reports (as applicable)

WBS/Task	Description	Go/No Go Criteria	Deliverable
OPTION 2: Process Development & NZW Rabbit Immunogenicity & Efficacy Study			
1.2.1.1: NZW rabbit Immunogenicity and Efficacy Study	Efficacy and immunogenicity testing using the development lot of the chosen product compared to AVA. Interim study data will be used as part of the Go/No Go decision for further development (cGMP manufacturing).	**Go**: PA specific immune response (TNA) and survival demonstrated in immunized rabbits is non-inferior to the AVA comparator **No Go**: Immunogenicity or survival following spore challenge not comparable to AVA · Investigation into the administered dose and stability of the product · Investigation of the specific aerosol exposure	Draft & final study protocol, survival data (14 days post-challenge), interim TNA data, draft & final study report, draft & final audit reports (as applicable)
1.1.1.3: Process Development (Dual-chamber Syringe)	Development studies required to establish appropriate CPPs for the formulation and product presentation in preparation for manufacturing scale-up	**Go**: Demonstration of successful lyophilization in the dual-chambered syringe **No-Go/Redirect**: The chosen product will not adequately lyophilize in the dual-chambered syringe. Additional development studies required	Draft & final process development protocols (syringe development), draft & final process development summary report, draft & final audit reports (as applicable)
1.4.1.1: Pre-IND Meeting	Necessary to obtain FDA concurrence on the development plan and the need for additional pre-clinical testing.	**Go**: Concurrence with the pre-clinical plan **No-Go/Redirect**: FDA does not agree with the planned toxicology study and clinical plan. The plan will be amended to satisfy the FDA review requirements	Draft & final pre-IND meeting supporting documentation package, draft & final pre-IND meeting agenda, draft & final FDA meeting minutes & correspondence

WBS/Task	Description	Go/No Go Criteria	Deliverable
OPTION 3: Engineering FDP Lot Manufacture			
1.1.1.4: Engineering FDP Lot (Dual-chamber Syringe)	This lot will be produced and fully analyzed to demonstrate that the lyo process can be done in a syringe and this lot will be used in the pre-clinical toxicology studies.	**Go**: Successful completion of engineering lot testing · *In situ* lyophilization in the dual-chambered syringe demonstrated · Reconstitution in dual-chambered syringe demonstrated · All release assay results within established ranges **No Go/Redirect**: Unable to demonstrate suitable lyophilization. Additional development studies required	Draft & final tech transfer report, draft & final batch record for engineering FDP lot (non-cGMP), draft & final process report, draft & final certificate of testing, draft & final audit reports (as applicable), draft & final quality agreement
OPTION 4: Supportive Activities GFY17			
1.5.1.2.1: Stability-Eng FDP Lot (Lyo rPA)-GFY17	Initiation of the 24 month stability testing for the engineering lot of lyo rPA FDP	**Go**: Product remains within analytical specifications. **No Go/Redirect**: The stability at 25°C fails. Additional development studies may be required	Draft & final engineering FDP lot stability protocol, draft & final stability table updates, draft & final audit reports (as applicable)
1.5.1.4.3: Stability-BDS cGMP Lot-GFY17	Ongoing stability testing of the cGMP rPA BDS	**Go**: Product remains within analytical specifications **No Go/Redirect**: The stability at -70°C fails. A new lot of BDS will be manufactured	Draft and final cGMP BDS lot stability table updates, draft & final audit reports (as applicable)
1.5.2.3: Storage (Product) - GFY17	Storage of development, engineering and cGMP product	N/A	Draft & final audit reports (as applicable)
1.5.3.3: Ref Std/Critical Reagent Mgmt - GFY17	· Reference Std Production - Engineering Lyo rPA (new) · Reference Standard Requalification (lot 11MF4907001-RS001) · rLF Requalification · IPA Diluent Requalification	**Go**: Standards or critical reagents remain within analytical specifications **No Go/Redirect**: Requalification fails. A new standard or critical reagent will be manufactured/qualified	Draft & final reference standard testing protocol (new), Draft & final qualification reports, draft & final reference standard qualification certificates, draft & final audit reports (as applicable)

WBS/Task	Description	Go/No Go Criteria	Deliverable
1.5.4.1: Storage (Non-clin/Clin Sample) GFY17	Controlled storage of samples collected in the non-clinical studies.	N/A	Draft & final audit reports (as applicable)
OPTION 5: GMP FDP Lot Manufacture and Supporting Stability GFY17			
1.1.1.5: cGMP FDP Lot (Dual-chamber Syringe)	cGMP material will be required for use in the Phase 1 clinical trial.	**Go**: Successful release of the cGMP clinical lot · Batch records reviewed and approved by the Quality unit · All release assay results within established ranges · Any deviations reviewed and successfully addressed **No Go/Redirect**: The cGMP clinical lot does not pass release testing · Full investigation into cGMP lot failure · Repeat of cGMP manufacturing may be necessary	Draft & final batch record (cGMP), draft & final certificate of analysis, batch disposition documentation, draft & final batch summary report, draft & final audit reports (as applicable), 500 units of final container product
1.5.1.3.1: Stability-cGMP FDP Lot (Lyo rPA)-GFY17	Initiation of stability testing of the cGMP lot to provide supportive data for Phase 1 clinical trial.	**Go**: Product remains within analytical specifications. Product demonstrates enhanced stability as compared to existing liquid stability data for six months at 25°C by iCE, LDS-PAGE and three months for IPA. **No Go/Redirect**: The stability at 25°C fails. A new lot of FDP will be manufactured	Draft & final cGMP FDP lot stability protocol, draft & final stability table updates, draft & final audit reports (as applicable)

WBS/Task	Description	Go/No Go Criteria	Deliverable
OPTION 6: IND-enabling Toxicology Study			
1.2.2.1: GLP Repeated-dose Toxicology Study (Rat)	The safety assessment will be required as part of the IND.	**Go**: Successful completion and final report of the toxicology study to support the Phase 1 Clinical Trial · A No Observable Adverse Effect Level (NOAEL) is demonstrated · No toxicity or safety concerns observed at the planned human dose **No Go**: A NOAEL dose is not defined	Draft & final study protocol, draft & final study report, draft & final audit report (as applicable), draft & final quality agreement
1.4.1.2: IND Submission	Required to initiate Phase 1 clinical trial	**Go**: FDA review reveals no clinical hold issues **No Go/Redirect**: Toxicity or safety concerns noted at the planned human dose may require additional toxicity studies or a lower than planned dose for the clinical trial	Draft & final IND submission, draft & final FDA correspondence
OPTION 7: Supportive Activities GFY18			
1.5.1.2.2: Stability-Eng FDP Lot (Lyo rPA)-GFY18	Ongoing stability program for the engineering lot of lyo rPA FDP	**Go**: Product remains within analytical specifications **No Go/Redirect**: The stability at 25°C fails. Additional development studies may be required	Draft & final engineering FDP lot stability table updates, draft & final audit reports (as applicable)
1.5.1.3.2: Stability-cGMP FDP Lot (Lyo rPA)-GFY18	Ongoing stability testing of the cGMP lot to provide supportive data for Phase I clinical trial.	**Go**: Product remains within analytical specifications **No Go/Redirect**: The stability at 25°C fails. A new lot of FDP will be manufactured	Draft & final cGMP FDP lot stability table updates, draft & final audit reports (as applicable)
1.5.1.4.4: Stability-BDS cGMP Lot-GFY18	Ongoing stability testing of the cGMP rPA BDS	**Go**: Product remains within analytical specifications **No Go/Redirect**: The stability at -70°C fails. A new lot of BDS will be manufactured	Draft & final cGMP BDS lot stability table updates, draft & final audit reports (as applicable)

WBS/Task	Description	Go/No Go Criteria	Deliverable
1.5.2.4: Storage (Product) - GFY18	Storage of development, engineering and cGMP product	N/A	Draft & final audit reports (as applicable)
1.5.3.4 - Ref Std/Critical Reagent Mgmt - GFY18	· Reference Standard Requalification (lot 11MF4907001-RS001) · rLF Requalification · IPA Diluent Requalification · Annual Reference Std Requalification (Eng Lyo rPA)	**Go**: Standards or critical reagents remain within analytical specifications **No Go/Redirect**: requalification fails. A new standard or critical reagent will be manufactured/qualified	Draft & final qualification reports, draft & final reference standard qualification certificates, draft & final audit reports (as applicable)
1.5.4.2: Storage (Non-clin/Clin Sample) GFY18	Required storage of samples obtained from the non-clinical and clinical studies	N/A	Draft & final audit reports (as applicable)
OPTION 8: Clinical Assessment & Supportive Activities GFY19-20			
1.3.1.1: Ph 1 Safety & Immunogenicity Clinical Trial	Comparison of the safety and immunogenicity of 50 mcg lyo rPA given im on two PEP schedules to AVA given sc on the proposed PEP schedule (0, 14, 28 days).	**Go**: No vaccine related SAEs. **No Go**: Unacceptable adverse event occurrence	Draft & final study protocol synopsis, draft & final clinical trial protocol, draft & final SMC Report template, draft & final eCRF, draft & final clinical quality management plan, draft & final statistical analysis plan, enrollment log reflecting final subject dosed, draft & final clinical study report, draft & final clinical manuscript, draft & final human subject IRB annual report, draft & final audit reports (as applicable)
1.5.1.2.3 - Stability-Eng FDP Lot (Lyo rPA)-GFY19	Ongoing stability program for the engineering lot of lyo rPA FDP	**Go**: Product remains within analytical specifications **No Go/Redirect**: The stability at 25°C fails. Additional development studies may be required	Draft & final engineering lot stability table updates, draft & final audit reports (as applicable)

WBS/Task	Description	Go/No Go Criteria	Deliverable
1.5.1.3.3 - Stability-cGMP FDP Lot (Lyo rPA)-GFY19	Ongoing stability testing of the cGMP lot to provide supportive data for Phase 1 clinical trial.	**Go**: Product remains within analytical specifications **No Go/Redirect**: The stability at 25°C fails. A new lot of FDP will be manufactured	Draft & final cGMP lot stability table updates, draft & final audit reports (as applicable)
1.5.2.5 - Storage (Product) - GFY19-20	Storage of development, engineering and cGMP product	N/A	Draft & final audit reports (as applicable)
1.5.3.5 - Ref Std/Critical Reagent Mgmt - GFY19	· Reference Standard Requalification (lot 11MF4907001-RS001) · rLF Requalification	**Go**: Standards or critical reagents remain within analytical specifications **No Go/Redirect**: requalification fails. A new standard or critical reagent will be manufactured/qualified	Draft & final qualification reports, draft & final reference standard qualification certificates, draft & final audit reports (as applicable)
1.5.4.3: Storage (Non-clin/Clin Sample) GFY19-20	Required storage of samples obtained from the non-clinical and clinical studies	N/A	Draft & final audit reports (as applicable)

1.4 Project Management

PharmAthene will provide for overall management, integration and coordination of all contract activities, including a technical and administrative infrastructure to ensure the efficient planning, initiation, implementation, direction, management and completion of all contract activities.

1.5 Communications

PharmAthene will establish effective communications with NIAID and its proposed subcontractors to discuss all aspects of program activities, anticipated problems or obstacles, proposed approaches to resolve problems and overcome obstacles, and future plans through regular biweekly (or as applicable), team meetings.

1.6 Regulatory Compliance

PharmAthene will be responsible for the development and implementation of data management and quality control systems/procedures, provide for statistical design and analysis of data; and ensure strict adherence to regulations and guidance for the activities to be undertaken.

1.7 Facilities

PharmAthene, in partnership with its selected subcontractors, operates facilities that are highly suitable for the development effort. All facilities meet local, state, and Federal requirements and are designed to promote safe and secure conduct of all contract operations. The proposed facilities have adequate floor space and equipment available to accommodate the projected needs throughout the performance period.

ATTACHMENT 2

INVOICE/FINANCING REQUEST AND CONTRACT FINANCIAL REPORTING INSTRUCTIONS FOR NIH COST-REIMBURSEMENT CONTRACTS, NIH(RC)-4

Format: Submit payment requests 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: Submit payment requests in the quantity specified in the Invoice Submission Instructions in Section G of the Contract Schedule.

Frequency: Payment requests shall not be submitted more frequently than once every two weeks in accordance with the Allowable Cost and Payment Clause incorporated into this contract. Small business concerns may submit invoices/financing requests more frequently than every two weeks.

Cost Incurrence Period: Costs incurred must be within the contract performance period or covered by precontract 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 the costs were incurred.

Contractor's Fiscal Year: Prepare payment requests in such a manner that the Government can identify costs claimed with the Contractor's fiscal year.

Currency: All NIH 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 shall not exceed the United States dollars authorized.

Costs Requiring Advance Approval: Costs requiring advance approval by the Contracting Officer, which are not set forth in the Contract Schedule shall be identified by the Contracting Officer's Authorization (COA) Number as a separate expenditure category on the payment request. In addition, the Contractor shall show any cost limitation or ceiling set forth in the Contract Schedule, i.e. an Advance Understanding, as a separate expenditure category on the payment request.

Invoice/Financing Request Identification: Identify each payment as either:

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

(b) **Completion Invoice**: Submit the completion invoice 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 all performance provisions have been completed.

(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. ***All information must be legible or the invoice will be considered improper and returned to the Contractor***.

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

(b) **Contractor's Name, Address, Point of Contact, TIN, and DUNS or DUNS+4 Number**: Show the Contractor's name and address exactly as they appear in the contract. Any invoice identified as improper will be sent to this address. Also include the name, title, phone number, and e-mail address of the Point of Contact in case of questions. If the remittance name differs from the legal business name, both names must appear on the invoice. Provide the Contractor's Federal Taxpayer Identification Number (TIN) and Data Universal Numbering System (DUNS) or DUNS+4 number. The DUNS number must identify the Contractor's name and address exactly as stated in the contract, and as registered in the System for Award Management (SAM) database.

When an approved assignment of claims has been executed, the Contractor shall provide the same information for the assignee as is required for the Contractor (i.e., name, address, point of contact, TIN, and DUNS number), with the remittance information clearly identified as such.

(c) **Invoice/Financing Request Number**: Identify each payment request by a unique invoice number, which can only be used one time regardless of the number of contracts or orders held by an organization. For example, if a contractor has already submitted invoice number 05 on one of its contracts or orders, it cannot use that same invoice number on any other contract or order. Payment requests with duplicate invoice numbers will be considered improper and returned to the contractor.

The NIH does not prescribe a particular numbering format but suggests using a job or account number for each contract and order followed by a sequential invoice number (example: 8675309-05). Invoice numbers are limited to 30 characters. There are no restrictions on the use of special characters, such as colons, dashes, forward slashes, or parentheses.

If all or part of an invoice is suspended and the contractor chooses to reclaim those costs on a supplemental invoice, the contractor may use the same unique invoice number followed by an alpha character, such as "R" for revised (example: 8675309-05R).

(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 (as applicable).

(f) **Contract Title**: Insert the contract title exactly as it appears on the cover page of the contract and/or Section G of the Contract Schedule.

(g) **Current Contract Period of Performance**: Insert the contract start date/effective date through the current completion date of the contract.

(h) **Total Estimated Cost of Contract/Order**: Insert the total estimated cost of the contract, exclusive of fee. If billing under an order, insert the total estimated cost of the order, exclusive of fee. For contracts/orders with options or incremental funding provisions, enter the amount currently obligated and available for payment.

(i) **Total Fixed-Fee**: Insert the total fixed-fee (where applicable). For contracts/orders with options or incremental funding provisions, enter the amount currently obligated and available for payment (where applicable). **Note**: *If the contract provides for another type of Fee, i.e. Award or Incentive Fee, insert the amount available to be earned as identified in the contract and indicate the type of fee to be billed on the payment request.*

(j) **Two-Way/Three-Way Match**: Identify whether payment is to be made using a two-way or three-way match. To determine required payment method, refer to the Invoice Submission Instructions in Section G of the Contract Schedule.

(k) **Office of Acquisitions**: Insert the name of the Office of Acquisitions, as identified in the Invoice Submission Instructions in Section G of the Contract Schedule.

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

(m) **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.

(n) **Amount Billed - Current Period**: Insert the amount claimed for the current billing period by major cost element, including any adjustments and 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) **Amount Billed - Cumulative**: Insert the cumulative amounts claimed by major cost element, including any adjustments and 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.

(p) **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) **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 Schedule) 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.)

2) **Fringe Benefits**: List any fringe benefits applicable to direct labor and billed as a direct cost. Cite the rate(s) used to calculate fringe benefit costs, if applicable.

3) **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 Contract of Government Property*). Show permanent research equipment separate from general purpose equipment.

   On a separate sheet of paper attached to the payment request, list each item for which reimbursement is requested. Precede the item with an asterisk (*) 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,

   - Contracting Officer Authorization (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.

4) **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.

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

6) **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.

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

8) **Subcontract Costs**: List subcontractor(s) by name and amount billed.

9) **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.

(q) **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.

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

(s) **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. **Note**: *If the contract provides for another type of Fee, i.e. Award or Incentive Fee, provide the same documentation for the amount claimed.*

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

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

(v) **Grand Totals**

(w) **Certification**: The Contractor shall include the following certification at the bottom of each payment request:

"Pursuant to authority vested in me, I certify that this voucher is correct and proper for payment."

Note: *The contract may require additional certifications (See Invoice Submission Instructions in Section G of the Contract Schedule)*

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 correspond to the Columns on the Sample Invoice/Financing Request.

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

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 Clause in the contract.

Modifications: List all new modification(s) (not previously reported) in the amount negotiated for an item 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.

SAMPLE INVOICE/FINANCING REQUEST AND CONTRACT FINANCIAL REPORT

(a) Designated Billing Office Name and Address: National Institutes of Health Office of Financial Management Commercial Accounts 2115 East Jefferson Street, Room 4B432, MSC 8500 Bethesda, MD 20892-8500 (b) Contractor's Name, Address, Point of Contact, TIN, and DUNS or DUNS+4 Number: **ABC CORPORATION** 100 Main Street Anywhere, U.S.A. Zip+4 Name, Title, Phone Number, and E-mail Address of Contractor's Point of Contact. DUNS or DUNS+4: _____ TIN: _____	(c) Invoice/Finance Request No.: _____ (d) Date Invoice/Financing Request Prepared: _____ (e) Contract No. and Order No. (if applicable): _____ (f) Contract Title: _____ (g) Current Contract Period of Performance: _____ (h) Total Estimated Cost of Contract/Order: _____ (i) Total Fixed Fee (if applicable): _____ (j) Two-Way Match: ____ Three-Way Match: ____ (k) Office of Acquisitions: _____ (l) Central Point of Distribution: _____

(m) This invoice/financing request represents reimbursable costs for the period from _____ to _____.

	Cumulative % of Effort/Hrs		Amount Billed				
Expenditure Category* A	Neg. B	Actual C	(n) Current D	(o) Cum E	Cost at Comp F	Contract Value G	Variance H
(p) 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							
(q) Cost of Money ___%							
(r) Indirect Costs ___%							
(s) Fixed Fee ___%							
(t) Total Amount Claimed							
(u) Adjustments							
(v) Grand Totals							

"Pursuant to authority vested in me, I certify that this voucher is correct and proper for payment."

_____ _____

(Name of Official) (Title)

*Attach details as specified in the contract or requested by the Contracting Officer

INCLUSION TABLE
This report format should NOT be used for data collection from study participants.

Principal Investigator/Project Director _____
(Last, First, Middle)

Grant Number (if known): _____

STUDY TITLE: _____

Total Enrollment: _____Protocol Number:_____

	American Indian or Alaskan Native	Asian or Pacific Islander	Black, not of Hispanic Origin	Hispanic	White, not of Hispanic Origin	Other or Unknown	Total
Female							
Male							
Unknown							
Total							

Safety and Health, HHSAR 352.223-70 (January 2006)

(a) To help ensure the protection of the life and health of all persons, and to help prevent damage to property, the Contractor shall comply with all Federal, State, and local laws and regulations applicable to the work being performed under this contract. These laws are implemented or enforced by the Environmental Protection Agency, Occupational Safety and Health Administration (OSHA) and other regulatory/enforcement agencies at the Federal, State, and local levels.

(1) In addition, the Contractor shall comply with the following regulations when developing and implementing health and safety operating procedures and practices for both personnel and facilities involving the use or handling of hazardous materials and the conduct of research, development, or test projects:

(i) 29 CFR 1910.1030, Bloodborne pathogens; 29 CFR 1910.1450, Occupational exposure to hazardous chemicals in laboratories; and other applicable occupational health and safety standards issued by OSHA and included in 29 CFR Part 1910. These regulations are available at: http://www.osha.gov.

(ii) Nuclear Regulatory Commission Standards and Regulations, pursuant to the Energy Reorganization Act of 1974 (42 U.S.C. 5801 et seq.). The Contractor may obtain copies from the U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

(2) The following Government guidelines are recommended for developing and implementing health and safety operating procedures and practices for both personnel and facilities:

(i) Biosafety in Microbiological and Biomedical Laboratories, CDC. This publication is available at http://www.cdc.gov/OD/ohs/biosfty/bmbl4/bmbl4toc.htm.

(ii) Prudent Practices for Safety in Laboratories (1995), National Research Council, National Academy Press, 500 Fifth Street, NW., Lockbox 285, Washington, DC 20055 (ISBN 0-309-05229-7). This publication is available at http://www.nap.edu/catalog/4911.html.

(b) Further, the Contractor shall take or cause to be taken additional safety measures as the Contracting Officer, in conjunction with the Contracting Officer's Technical Representative or other appropriate officials, determines to be reasonably necessary. If compliance with these additional safety measures results in an increase or decrease in the cost or time required for performance of any part of work under this contract, the Contracting Officer will make an equitable adjustment in accordance with the applicable "Changes" clause set forth in this contract.

(c) The Contractor shall maintain an accurate record of, and promptly report to the Contracting Officer, all accidents or incidents resulting in the exposure of persons to toxic substances, hazardous materials or hazardous operations; the injury or death of any person; or damage to property incidental to work performed under the contract and all violations for which the Contractor has been cited by any Federal, State or local regulatory/enforcement agency. The report shall include a copy of the notice of violation and the findings of any inquiry or inspection, and an analysis addressing the impact these violations may have on the work remaining to be performed. The report shall also state the required action(s), if any, to be taken to correct any violation(s) noted by the Federal, State or local regulatory/enforcement agency and the time frame allowed by the agency to accomplish the necessary corrective action.

(d) If the Contractor fails or refuses to comply with the Federal, State or local regulatory/enforcement agency's directive(s) regarding any violation(s) and prescribed corrective action(s), the Contracting Officer may issue an order stopping all or part of the work until satisfactory corrective action (as approved by the Federal, State or local regulatory/enforcement agencies) has been taken and documented to the Contracting Officer. No part of the time lost due to any stop work order shall be subject to a claim for extension of time or costs or damages by the Contractor.

(e) The Contractor shall insert the substance of this clause in each subcontract involving toxic substances, hazardous materials, or hazardous operations. The Contractor is responsible for the compliance of its subcontractors with the provisions of this clause.

(End of clause)

RESEARCH PATIENT CARE COSTS — NIH(RC)-11

(a) Research patient care costs are the costs of routine and ancillary services provided to patients participating in research programs described in this contract.

(b) Patient care costs shall be computed in a manner consistent with the principles and procedures used by the Medicare Program for determining the part of Medicare reimbursement based on reasonable costs. The Diagnostic Related Group (DRG) prospective reimbursement method used to determine the remaining portion of Medicare reimbursement shall not be used to determine patient care costs. Patient care rates or amounts shall be established by the Secretary of HHS or his duly authorized representative.

(c) Prior to submitting an invoice for patient care costs under this contract, the contractor must make every reasonable effort to obtain third party payment, where third party payors (including Government agencies) are authorized or are under a legal obligation to pay all or a portion of the charges incurred under this contract for patient care.

(d) The contractor must maintain adequate procedures to identify those research patients participating in this contract who are eligible for third party reimbursement.

(e) Only those charges not recoverable from third party payors or patients and which are consistent with the terms and conditions of the contract are chargeable to this contract.

DISCLOSURE OF LOBBYING ACTIVITIES

Complete this form to disclose lobbying activities pursuant to 31 U.S.C. 1352

(See reverse for public burden disclosure.)

Approved by OMB
0348-0046

1. Type of Federal Action:	**2. Status of Federal Action:**	**3. Report Type:**
☐ a. contract b. grant c. cooperative agreement d. loan e. loan guarantee f. loan insurance	☐ a. bid/offer/application b. initial award c. post-award	☐ a. initial filing b. material change **For Material Change Only:** year _____ quarter _____ date of last report _____

4. Name and Address of Reporting Entity:	**5. If Reporting Entity in No. 4 is a Subawardee, Enter Name and Address of Prime:**
☐ Prime ☐ Subawardee Tier _____, *if known*: **Congressional District**, *if known*: 4c	**Congressional District**, *if known*:
6. Federal Department/Agency:	**7. Federal Program Name/Description:** CFDA Number, *if applicable*: _____
8. Federal Action Number, *if known*:	**9. Award Amount**, *if known*: $
10. a. Name and Address of Lobbying Registrant (*if individual, last name, first name, MI*):	**b. Individuals Performing Services** (*including address if different from No. 10a*) (*last name, first name, MI*):
11. Information requested through this form is authorized by title 31 U.S.C. section 1352. This disclosure of lobbying activities is a material representation of fact upon which reliance was placed by the tier above when this transaction was made or entered into. This disclosure is required pursuant to 31 U.S.C. 1352. This information will be available for public inspection. Any person who fails to file the required disclosure shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each such failure.	Signature: _____ Print Name: _____ Title:_____ Telephone No.: _____ Date: _____

Federal Use Only:	Authorized for Local Reproduction Standard Form LLL (Rev. 7-97)

INSTRUCTIONS FOR COMPLETION OF SF-LLL, DISCLOSURE OF LOBBYING ACTIVITIES

This disclosure form shall be completed by the reporting entity, whether subawardee or prime Federal recipient, at the initiation or receipt of a covered Federal action, or a material change to a previous filing, pursuant to title 31 U.S.C. section 1352. The filing of a form is required for each payment or agreement to make payment to any lobbying entity 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 a covered Federal action. Complete all items that apply for both the initial filing and material change report. Refer to the implementing guidance published by the Office of Management and Budget for additional information.

1. Identify the type of covered Federal action for which lobbying activity is and/or has been secured to influence the outcome of a covered Federal action.

2. Identify the status of the covered Federal action.

3. Identify the appropriate classification of this report. If this is a follow up report caused by a material change to the information previously reported, enter the year and quarter in which the change occurred. Enter the date of the last previously submitted report by this reporting entity for this covered Federal action.

4. Enter the full name, address, city, State and zip code of the reporting entity. Include Congressional District, if known. Check the appropriate classification of the reporting entity that designates if it is, or expects to be, a prime or subaward recipient. Identify the tier of the subawardee, e.g., the first subawardee of the prime is the 1st tier. Subawards include but are not limited to subcontracts, subgrants and contract awards under grants.

5. If the organization filing the report in item 4 checks "Subawardee," then enter the full name, address, city, State and zip code of the prime Federal recipient. Include Congressional District, if known.

6. Enter the name of the Federal agency making the award or loan commitment. Include at least one organizational level below agency name, if known. For example, Department of Transportation, United States Coast Guard.

7. Enter the Federal program name or description for the covered Federal action (item 1). If known, enter the full Catalog of Federal Domestic Assistance (CFDA) number for grants, cooperative agreements, loans, and loan commitments.

8. Enter the most appropriate Federal identifying number available for the Federal action identified in item 1 (e.g., Request for Proposal (RFP) number; Invitation for Bid (IFB) number; grant announcement number; the contract, grant, or loan award number; the application/proposal control number assigned by the Federal agency). Include prefixes, e.g., "RFP-DE-90-001."

9. For a covered Federal action where there has been an award or loan commitment by the Federal agency, enter the Federal amount of the award/loan commitment for the prime entity identified in item 4 or 5.

10. (a) Enter the full name, address, city, State and zip code of the lobbying registrant under the Lobbying Disclosure Act of 1995 engaged by the reporting entity identified in item 4 to influence the covered Federal action.

    (b) Enter the full names of the individual(s) performing services, and include full address if different from 10 (a). Enter Last Name, First Name, and Middle Initial (MI).

11. The certifying official shall sign and date the form, print his/her name, title, and telephone number.

Exhibit 31.1

Certification of Principal Executive Officer
Pursuant to SEC Rule 13a-14(a)/15d-14(a)

I, John M. Gill, certify that:

1. I have reviewed this Amendment No. 1 to the Quarterly Report on Form 10-Q/A of PharmAthene, Inc.; and

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.

Dated: November 22, 2016

/s/ John M. Gill
Name: John M. Gill
Title: President and Chief Executive Officer

Exhibit 31.2

Certification of Principal Financial Officer
Pursuant to SEC Rule 13a-14(a)/15d-14(a)

I, Philip MacNeill, certify that:

1. I have reviewed this Amendment No. 1 to the Quarterly Report on Form 10-Q/A of PharmAthene, Inc.; and

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.

Dated: November 22, 2016

/s/ Philip MacNeill
Name: Philip MacNeill
Title: Vice President, Chief Financial Officer, Treasurer and Secretary