18-02587-E

Debra Smetana
ktMINE
940 West Adams
Suite 100
Chicago, IL 60607

2/20/2018

U.S. Securities & Exchange Commission
Office of FOIA and Privacy Act Operations
100 F Street, NE
Mail Stop 2465
Washington, DC 20549-5100

Dear Sir or Madam:

Under the Freedom of Information Act (FOIA), please send the confidential portions (i.e. unredacted documents) corresponding to the expiration of the Confidential Treatment Order submitted under Rule 24b-2 of the following company

Exhibit 10.1 to the 9/30/14 10-Q, filed by Novavax, Inc. on 11/6/2014

We authorize $0 for search and review fees, as these documents have been previously requested. Please contact me if search will require additional fees beyond the above mentioned. My daytime phone number is (312) 667-0267

Sincerely,

Debra Smetana

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
STATION PLACE
100 F STREET, NE
WASHINGTON, DC 20549-2465

Office of FOIA Services

March 07, 2018

Ms. Debra Smetana
ktMine
940 West Adams, Suite 100
Chicago, IL 60607

RE: Freedom of Information Act (FOIA), 5 U.S.C. § 552
Request No. 18-02587-E

Dear Ms. Smetana:

This letter is in response to your request, dated and received in this office on February 20, 2018, for an un-redacted copy of Exhibit 10.1, to the September 30, 2014 Form 10-Q, filed by Novavax, Inc. on November 6, 2014.

Our search for responsive records has resulted in the retrieval of the above-requested exhibit, totaling 42 pages of records that may be responsive to your request. They are being provided to you with this letter.

If you have any questions, please contact me at wadeo@sec.gov or (202) 551-8323. You may also contact me at foiapa@sec.gov or (202) 551-7900. You also have the right to seek assistance from Ray J. McInerney as a FOIA Public Liaison or contact the Office of Government Information Services (OGIS) for dispute resolution services. OGIS can be reached at 1-877-684-6448 or Archives.gov or via e-mail at ogis@nara.gov.

Sincerely,

Ollie R. Wade

Ollie R. Wade
FOIA Research Specialist

Enclosures

10.1

RECEIVED
MAY 19 2011
OFFICE OF THE SECRETARY

AWARD/CONTRACT	1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)	RATING	PAGE 1 OF PAGES 28
2. CONTRACT (Proc. Inst. Indent.) NO. HHSO100201100012C	3. EFFECTIVE DATE 02/24/2011	4. REQUISITION/PURCHASE REQUEST/PROJECT NO. OS58212	

5. ISSUED BY CODE
HHS/OS/ASPR/BARDA
330 Independence Avenue, SW, Room G640
Washington, DC 20201

6. ADMINISTERED BY (If other than Item 5) CODE

7. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and ZIP Code)
Novavax, Inc.
9920 Belward Campus Drive
Rockville, MD 20850

DUNS: 808837520

8. DELIVERY
☐ FOB ORIGIN ☒ OTHER (See below)

9. DISCOUNT FOR PROMPT PAYMENT
N/A

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

CODE FACILITY CODE

11. SHIP TO/MARK FOR CODE
See Article D.1.

12. PAYMENT WILL BE MADE BY CODE
See Article G.4.

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

14. ACCOUNTING AND APPROPRIATION DATA
75X0140 1994010 26201 $97,260,881.00

15A. ITEM NO.	15B. SUPPLIES/SERVICES	15C. QUANTITY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT
	Title: Advanced Development of Recombinant Influenza Vaccine Products and Manufacturing Capabilities for Pandemic Preparedness 02/24/2011 - 02/23/2014 (Base Period-36 mos.)	1	Job	$97,260,881.00	$97,260,881.00

15G. TOTAL AMOUNT OF CONTRACT $ 97,260,881.00

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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 terms listed above and on any continuation sheets. This award consummates the contract which consists of the following documents: (a) the Government's solicitation and your offer, and (b) this award/contract. No further contractual document is necessary.

19A. NAME AND TITLE OF SIGNER (Type or Print)
Rahul Singhvi, President and C.E.O.

20A. NAME OF CONTRACTING OFFICER
RoseMary Mann

19B. NAME OF CONTRACTOR
BY _____ (Signature of person authorized to sign)

19C. DATE SIGNED
18 Feb, 2011

20B. UNITED STATES OF AMERICA
BY _____ (Signature of Contracting Officer)

20C. DATE SIGNED
2/24/2011

AUTHORIZED FOR LOCAL REPRODUCTION
Previous edition is usable

STANDARD FORM 26 (REV. 4/2008)
Prescribed by GSA - FAR (48 CFR) 53.214(a)

ADVANCED DEVELOPMENT OF RECOMBINANT INFLUENZA VACCINE PRODUCTS AND MANUFACTURING CAPABILITIES FOR PANDEMIC PREPAREDNESS

SECTION B--SUPPLIES OR SERVICES AND PRICES/COSTS

For the purposes of this contract, the U.S. is defined as the fifty states, the District of Columbia, Puerto Rico and all U.S. territories. The terms "Government" and "USG" are collectively defined to mean the Federal Government of the U.S.

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

This project from the Department of Health and Human Services (HHS) through the Biomedical Advanced Research and Development Authority (BARDA) within the Office of the Assistant Secretary for Preparedness and Response (ASPR), focuses on the advanced development of recombinant seasonal and pandemic-like influenza vaccines utilizing hemagglutinin genes or proteins (plasmid DNA, virus-vectors, peptides, subunit proteins and virus-like particles) towards U.S.-licensure in exchange for a commitment to establish a rapid surge capacity for pandemic vaccine.

ARTICLE B.2. CONTRACT LINE ITEMS NUMBERS (CLINs)

(a) Contract Type

This is a multiple year, cost reimbursement type contract with option periods. This contract shall contain a Base Period, an Option Period One and an Optional CLIN 0015. The exercise of an option shall be in accordance with FAR 52.217-9, Option to Extend the Term of the Contract (March 2000).

(b) Consideration and Payment (CPFF)

This is a cost plus fixed fee (CPFF) contract. In consideration for completion of the work, described under the Base Period (CLINs 0001 through 0010) and in accordance with the Statement of Work (Section C), the Contractor shall be paid an amount not to exceed $97,260,881 of which $90,923,009 represents the estimated reimbursable costs and $6,337,871 represents the fixed fee.

The amount currently allotted for the Base Period shall cover a 36 month performance period.

BASE PERIOD (36 Months)

CLIN	SUPPLIES / SERVICES	QTY/UNIT	EST. COST	FIXED FEE	TOTAL EST. CPFF
0001	**Product Development Plan** (Milestone 1)	**1 Job**	**$300,671**	**$20,749**	**$321,420**
0002	**Clinical Development and Regulatory Plan** (Milestone 2)	**1 Job**	**$105,380**	**$7,279**	**$112,659**
0003	**Manufacturing Facility Plan** (Milestone 3)	**1 Job**	**$1,062,397**	**$73,792**	**$1,136,189**
0004	**Feasibility Plan** (Milestone 4)	**1 Job**	**$244,073**	**$16,835**	**$260,908**
0005A	**Contractor Defined Milestones - Recombinant Seasonal Influenza Vaccine Milestones** (Milestone 5A)	**1 Job**	**$60,233,298**	**$4,199,964**	**$64,433,262**

0005B	**Contractor Defined Milestones – Recombinant Pandemic Influenza Vaccine Milestones** (Milestone 5B)	**1 Job**	**$28,971,571**	**$2,018,864**	**$30,990,435**
0006	**Draft Security Plan**	**Not Separately Priced (NSP)**	**NSP**	**NSP**	**NSP**
0007	**Final Security Plan**	**Not Separately Priced (NSP)**	**NSP**	**NSP**	**NSP**
0008	**Technical Progress Reports (Including EVM) and Executive Summary**	**36 reports of each**	**$0**	**$0**	**$0**
0009	**Draft Final Report**	**Not Separately Priced (NSP)**	**NSP**	**NSP**	**NSP**
0010	**Final Report**	**1 Report**	**$5,619**	**$389.00**	**$6,008**

OPTION PERIOD ONE (24 Months)

Shall the Government decide to exercise an Option Period One upon completion of CLIN 0010, the Contractor shall provide the additional Contractor Defined Milestones for recombinant seasonal and pandemic influenza vaccines, as stated in the Contractor's technical proposal dated February 04, 2011, Appendix X, pages 1-3. In addition, the Contractor shall provide a separate timeline and milestone plan for the additional Contractor Defined Milestones.

Optional CLIN	SUPPLIES / SERVICES	QTY/UNIT	EST. COST	FIXED FEE	TOTAL EST. CPFF
0011A	**Additional Contractor Defined Milestones - Recombinant Seasonal Influenza Vaccine**	**1 Job**	**$24,419,736**	**$1,693,603**	**$26,113,339**
0011B	**Additional Contractor Defined Milestones – Recombinant Pandemic Influenza Vaccine**	**1 Job**	**$49,108,323**	**$3,422,748**	**$52,531,071**
0012	**Technical Progress Reports (Including EVM) and Executive Summary**	**24 reports of each**	**$156,890**	**$10,976**	**$167,866**
0013	**Draft Final Report**	**Not Separately Priced (NSP)**	**NSP**	**NSP**	**NSP**
0014	**Final Report**	**1 Report**	**$79,920**	**$5,512**	**$85,432**

OPTIONAL CLIN 0015

Shall the Government decide to exercise Optional CLIN 0015 for drug substance manufacturing in response to a Public Health Emergency (for use under an Emergency Use Authorization (EUA)) and/or the Government foresees to have vaccines be placed in the Strategic National Stockpile (SNS), the Contractor shall manufacture a recombinant seasonal, pre-pandemic or pandemic influenza vaccine candidate.

Optional CLIN	SUPPLIES / SERVICES	QTY/UNIT	UNIT PRICE	EST. COST	FIXED FEE	TOTAL EST. CPFF
0015	**The Contractor shall manufacture bulk Recombinant Influenza Vaccine candidate***	**150,000 / 15 mcg dose equivalents (Bulk)****	**$18.15**	**$2,722,488**	**$188,313**	**$2,910,801**

*** Strain selection to be supplied by HHS.**
****In the event of such an emergency, the Contracting Officer reserves the right to increase the quantity amount in order to meet the Governments' needs.**

ARTICLE B.3. PROVISIONS APPLICABLE TO DIRECT COSTS

Notwithstanding the clause, 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:

a) Acquisition, by purchase or lease, of any interest in real property;
b) Special rearrangement or alteration of facilities;
c) Purchase of 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.);
d) Travel Costs;
e) Consultant Costs;
f) Subcontracts;
g) Patient Care Costs; and
h) Accountable Government Property (defined as both real and personal property with an acquisition cost of $1,000 or more and a life expectancy of more than two years) and "sensitive items" (defined and listed in the Contractor's Guide of Government Property), regardless of acquisition value.

ARTICLE B.4. ADVANCE UNDERSTANDINGS

(a) Termination of Contract

If the Contractor fails to meet the milestones, within the specified time periods as stated in the statement of work, the Government has the right to terminate the contract for default, in accordance with FAR 52.249-6, Termination (Cost-Reimbursement) (May 2004).

(c) In Process Review

An In Process Review (IPR) will be conducted at the discretion of the Government eighteen (18) months after contract award and prior to the exercise of Option Period One, to discuss the progression of the milestones. Furthermore, the Government reserves the right to revise the milestones and budget pending program development status.

SECTION C – DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

DEFINITIONS – For the purpose of this Section

"Freedom to Operate" – ensures that the commercial production, marketing and use of the Contractor's new product, process and service do not infringe the intellectual property rights of others.

ARTICLE C.1. STATEMENT OF WORK

A. PURPOSE

The purpose of this contract is to support (1) industrial, advanced-stage development of recombinant seasonal and pandemic influenza vaccines leading towards U.S. licensure, (2) expansion of domestic influenza vaccine manufacturing surge capacity, and (3) to reduce the timeline for manufacturing and release of influenza vaccines during a pandemic. The proposed recombinant

influenza vaccines shall be produced at commercial-scale levels as licensable products in U.S.-based manufacturing facilities and shall provide sufficient surge capacity to contribute substantially to U.S. and, ideally, global vaccine needs during an influenza pandemic.

Activities that may be supported by this contract shall include: (1) clinical lot manufacturing including consistency lots of recombinant seasonal and pandemic-like influenza vaccine, (2) clinical evaluation studies of the recombinant vaccine strategy for safety and immunogenicity including clinical assay development, (3) process and manufacturing scale-up development, (4) product lot release assay development and process validation, (5) product-dedicated manufacturing equipment, facility concept design and facility validation. U.S. Government support shall not be provided for building a manufacturing facility or purchasing an existing facility. Finally, development of recombinant pandemic influenza virus vaccine shall occur in parallel with the Contractor's own advanced product development, towards licensure, of a recombinant seasonal influenza vaccine.

This advanced development contract is milestone-driven and funding may occur in phases following periodic assessments of progress by HHS. Continuation of effort on initial and subsequent milestones and associated funding will be based on Contractor performance, timeliness, quality of deliverables, availability of other vaccine manufacturing strategies and products deemed more advantageous to the U.S. Government, and consultations between the Contractor and HHS.

STATEMENT OF WORK

Independently and not as an agent of the government, the Contractor shall furnish all the necessary services, qualified personnel, materials, equipment, and facilities not otherwise provided by the government as needed to perform the work described below.

The Contractor shall perform the work in accordance with the Contractor's Work Plan (CWP) (or Summary of CWP) and the Contractor's Gantt chart referenced in Section J and attached to this contract. The contract schedule milestones takes precedence over discrepancy with the attachments.

The following Milestone Plans are required to describe the activities that the Contractor will perform to successfully meet the objectives of the contract. The Contractor shall demonstrate their full understanding of the key elements essential to complete the requirements, including how each milestone plan is organized, staffed and managed. The completeness and quality of the Contractor's milestone plans and supporting data will be evaluated in terms of relative risk and the likelihood of successful completion of the project. The level of detail contained in the milestone plans shall be sufficient to facilitate management of and execution of the contract by the Contractor. Acceptable milestone plans are a requirement of this contract. The Contracting Officer may modify this contract, as described in Milestones 5a and 5b, to incorporate the Contractor Defined Milestones, work breakdown structures and Gantt charts provided and accepted in Milestones 1-4.

Milestones

I. Milestone 1: Within three (3) months of contract award, the Contractor shall provide to HHS for review and acceptance a comprehensive milestone-driven **Product Development Plan** for recombinant seasonal and pandemic influenza vaccines. The Plan shall be inclusive of pre-clinical and clinical activities performed and completed prior to a contract award and those clinical and manufacturing activities to be performed post-contract award. The Plan shall be a high-level overview and include the following elements:

A. Gantt chart timeline or equivalent.

B. Description of the process development and scale-up of recombinant vaccine manufacturing.

C. Description of clinical and consistency lot manufacturing to support process validation, clinical evaluation and FDA Center for Biologics Evaluation and Research (CBER) product licensure.

D. Description of the general clinical development plan including development and validation of clinical sample assays.

E. Description of product lot release assay development including assay specifications and validation.

F. Regulatory master plan that focuses on the critical pathway to product licensure.

G. Cost-accounting system based on the original budget estimates (that includes earned value management) to monitor all costs related to the contract award for both prime and sub-Contractors on a real time basis.

II. Milestone 2: Within three (3) months of contract award, the Contractor shall submit to HHS for review and acceptance, a comprehensive, integrated **Clinical Development and Regulatory Plan.** The following issues shall be addressed in the Plan:

A. A **summary of pre-clinical studies** including consultation(s) with the FDA Center for Biologics Evaluation and Research (CBER) incorporated as an appendix to the milestone report.

B. A **detailed description of clinical evaluation** shall be integrated with the manufacturing plans using the most current and available information including consultation with CBER. Clinical trials performed as a result of this solicitation shall include any Phase 1, Phase 2, and Phase 3 trials needed to achieve U.S. licensure. Trials shall include children, adults, and the elderly, as needed, to support licensure for both low and high-risk populations. Given the duration, cost, and importance of clinical trials, the plan for each clinical trial shall clearly indicate key outcomes, populations, study sites and collaborators, analytic strategy, sample size, timelines, and other key components. Studies related to pandemic –like vaccine shall be done using recombinant influenza vaccine to a relevant influenza virus strain to be designated by HHS (i.e., H5N1, H1N1, etc.) A summary of available clinical lot manufacturing results, provisional lot release specifications, completed Phase 1 trials and any additional stages of product development that have been completed shall be incorporated as an appendix to the milestone report.

C. A **detailed description of regulatory activities** shall be integrated with all products, clinical testing and manufacturing activities using the most current and available information, including consultation with CBER. A risk assessment and mitigation plan addressing potential manufacturing, clinical and regulatory obstacles that might prevent or delay licensure as well as a plan for the production and distribution of vaccine in the case of emergency use authorization shall be included. Issues suitable for risk assessment include recombinant DNA constructs, cell lines, assay development, process yields and facility management. Mitigation plans shall include decision trees where applicable.

Many of the required elements may be satisfied by inclusion of the Contractor's Investigational New Drug (IND) application and relevant supplements.

III. Milestone 3: Within nine (9) months of contract award, the Contractor shall provide HHS for review and acceptance a **Manufacturing Facility Plan** describing the design, construction, commissioning, qualification and validation of a U.S.-based facility to produce the Contractor's recombinant seasonal and pandemic-like influenza vaccines. The Plan shall contain appropriate information concerning the following elements:

A. **Site selection criteria**, including site user requirement specifications, descriptions of site utilities and infrastructure, descriptions of local, state and federal permitting issues and security planning considerations.

B. A **facility regulatory compliance plan** that addresses cGMP standards, NIH, CDC, USDA and WHO biosafety standards, USDA animal testing standards, National Fire Protection Agency standards, DHS security issues and OSHA compliance.

C. **Manufacturing processes** that includes descriptions of upstream and downstream processing, formulation, filling and finishing unit operations, bulk and finished product acceptance specifications, overall capacity needed to meet contract requirements, manufacturing support operations such as solution preparation, storage and distribution, glassware washing and sterilization, clean-in-place and steam-in-place operations, a risk management plan at each stage of production, process flow diagrams, equipment capacity calculations, an automation plan and an equipment list detailing sizing capacity criteria, utility requirements, dimensions, clearances weights, mounting and purchasing lead times.

D. **Architectural/structural plans** that includes concept functional designs, descriptions, and diagrams of space requirements, adjacency plans, floor plans, equipment layouts, material, product and personnel flows, solid, liquid contaminated and other waste flows, and an air balance description or diagram detailing zoning, pressurization, air flows and air quality classification.

E. **Process and building/ mechanical engineering** including energy balances, utility flow diagrams, automation plan, equipment lists and a preliminary layout.

F. A **proposed construction schedule** including installation, commissioning and installation/operational/performance qualification and a risk mitigation analysis.

G. A **description of the manufacturing facility quality assurance and regulatory acceptance** including quality systems, the validation master plan and regulatory milestones.

The manufacturing facility and process shall be maintained in compliance with current Good Manufacturing Practices, World Health Organization guidelines for pandemic influenza vaccine manufacturing and current biosafety/research guidelines from the CDC, NIH, and the USDA. Ability to meet standards for Biosafety Level (BSL) 2 + and 3 as described in relevant guidelines may be necessary, if the Contractor will be handling and testing highly pathogenic avian influenza viruses or derivatives to generate recombinant pandemic-like influenza vaccines.

IV. Milestone 4: Within twelve (12) months of contract award, the Contractor shall provide HHS for review and acceptance a **Feasibility Plan** to manufacture, test, and release final container product containing recombinant pandemic-like influenza vaccine within 12 weeks of a pandemic declaration with a surge capacity of 50 million doses within six (6) months. The Plan shall include the following elements:

A. A **process description**, including a summary of process data that describes the yield and purification efficiencies of key process steps.

B. A **comparison of process data** that describes the significance of process scale-up and strain variability on production capacity.

C. **Proposed production schedules** including detailed timelines for each production step from accessibility of pandemic influenza viral nucleotide sequences or receipt of pandemic influenza virus reference strain to release of initial lot(s) of 50 million doses of final container vaccine product during a pandemic. Additionally, a description of material management and the number of doses of vaccine released each week after pandemic declaration shall be provided.

D. A bulk and fill-finish **manufacturing capacity analysis** for pandemic influenza vaccines.

E. A **description of process optimization activities**.

F. **Dose calculations and contingency plans** to address the need for higher dosages of the active product ingredient.

G. A **pre-pandemic facility management plan** including a pandemic preparedness plan.

H. A **pandemic facility management plan** including change procedures for pandemic operations and operation under Emergency Use Authorization (EUA).

V. Milestone 5a and 5b: **Contactor Defined Milestones.** The Contractor shall provide a work breakdown structure including comprehensive and integrated timelines (Gantt chart or equivalent) and major milestones to complete the remaining scope of work as relevant given the stage of vaccine development and evaluation toward product licensure. The Contractor shall propose milestones, at which time data will be presented, summarizing results of prior activities and new plans and protocols that will be submitted for review and approval in order to guide all subsequent activities. Milestones for recombinant seasonal (5a) and pandemic-like (5b) influenza vaccines shall be provided to track program progress and cost reimbursements. Potential milestones may include manufacturing of an investigational lot of vaccine, validation of facilities, systems and equipment, validation of Quality Control product lot release methods, validation of manufacturing processes, stability study programs, consistency lot manufacturing, completion of a clinical trial and progress to a new phase of vaccine evaluation, submission of a license application, GMP Consistency Lots Manufacturing, Phase 3 Lots Testing and Release, Reproductive Toxicology study(ies), Phase 2 Clinical trials in healthy adults, etc. Following the Project Officer/Contracting Officer's Technical Representative (COTR) acceptance of the Contractor Defined Milestones, the Contracting Officer may modify this contract to incorporate the Contractor Defined Milestones, work breakdown structure and Gantt chart.

VI. **Manufacturing Standards**: The USG reserves the right to inspect the Contractor's facilities for cGMP compliance. HHS will audit manufacturing, testing and other relevant sites. Focus areas will include manufacturing, quality systems and regulatory affairs relative to the contract milestone activities within six (6) months of contract award. Any deficiencies observed in the audit will require remediation. Within three (3) months after receiving the audit report, a time-plan for remediation must be in place and remediation shall be complete within the Base Period of the contract.

[END OF STATEMENT OF WORK]

Meetings and Conferences:

The Contractor shall participate in regular meetings to coordinate and oversee the contract effort as directed by the Project Officer/COTR. Such meetings may include, but are not limited to, meetings of all Contractors and subcontractors to discuss clinical manufacturing progress, product development, product assay development, scale up manufacturing development, clinical sample assays development, clinical study designs and regulatory issues, meetings with individual Contractors and other HHS officials to discuss the technical, regulatory, and ethical aspects of the program; and meetings with technical consultants to discuss technical data provided by the Contractor. Monthly teleconferences with the Contractor and subcontractors with HHS officials will be held at times and dates to be determined to review technical and product development progress, except during clinical lot manufacturing when meetings shall be held on a weekly basis. In addition, the Project Officer/COTR may schedule progress reviews, including quarterly progress reviews, on-site at the Contractor's facilities and other locations.

ARTICLE C.1.1. SECURITY OF CONTRACT OPERATIONS AND INFORMATION TECHNOLOGY

The work performed for development, manufacture, transport, storage and distribution will be performed under a detailed security plan that ensures against theft, tampering or destruction of the specific pertinent product-related material, equipment, documents, information, and data. The Contractor shall develop a written **Draft Security Plan**, for the protection of physical facilities, using, for example, fencing, controlled access, surveillance equipment, 2-person integrity rule, tamper evident packaging, and armed guards. The Contractor shall submit the Draft Security Plan to the Contracting Officer and Project Officer/COTR within 30 days after contract award. The Draft Security Plan shall describe the procedures to be utilized to manage and monitor the general internal operations of the firm and a description of the Contractor's facility(ies) in which the work will be performed and related activity conducted, including work by any subcontractors and consultants. The Draft Security Plan shall also include the Contractor's procedures for screening and background investigations of all employees, subcontractors and consultants who have access to the development, manufacturing, transport, storage, and distribution of the product. Such background inquiries and screening shall include, but not be limited to, education, previous employment, fingerprints and complete criminal history (FBI, state, and local), credit reports, civil actions, DMV, social security account number verification, drug testing, and references. Screening data shall include the employee's full name, any aliases, date(s) of birth, and Social Security numbers and other identifying numbers as appropriate, e.g., Passport number. At time of award, the USG can audit and review at its discretion the Contractor's personnel records in order to confirm compliance with personnel screening and background investigation requirements. Such access will also include interviews with relevant Contractor human resources supervisory and hiring personnel.

This plan shall ensure confidentiality, integrity of, and timely access by authorized individuals to data, information and information technology systems, consistent with OMB Circular A-130, Appendix III. This plan shall also address the Contractor's security-related due diligence on public information, marketing, advertising, including use of web site(s) impacting product and supply chain security.

This plan shall also include the security measures to be used to protect the medical countermeasure to be stored at the Contractor's facility (e.g., refrigeration/freezer alarm systems, backup electrical power generator systems, etc.), and the contingency plan to accommodate any manufacturing and storage problems caused by natural or man-made disasters, power loss, refrigerant loss, equipment failures, etc.

The Project Officer/COTR, Contracting Officer and the Information Protection and Systems Security (IPASS) Coordinator will review the plan and submit comments to the Contractor within 10 business days after receipt. The Contractor shall revise the Security Plan, if required, and submit a **Final Security Plan** to the Government within 30 days of notification. Upon completion of all the required security measures, the Contractor shall supply to the Project Officer/COTR a letter certifying compliance. Performance of work under this contract shall be in accordance with this written Security Plan.

ARTICLE C.2. EARNED VALUE MANAGEMENT (EVM)

FAR Clause 52.234-3, Notice of Earned Value Management System – Post Award IBR (July 2006) and FAR Clause 52.234-4, Earned Value Management System (July 2006) are incorporated herein by reference.

C.2.1 Managerial Approach

The Contractor shall deliver a Management Plan that explains how the Contractor shall provide for the effective and efficient management of the technical, administrative, logistical, and support functions described in this statement of work. This Earned Value Project Management System shall meet the Seven Principles of Program Performance Based Management. The Seven Principles are:

1. Plan all work scope for the program to completion.
2. Break down the program work scope into finite pieces that can be assigned to a responsible person or organization for control of technical, schedule, and cost objectives.
3. Integrate program work scope, schedule, and cost objectives into a performance measurement baseline plan against which accomplishments may be measured. Control changes to the baseline.
4. Use actual cost incurred and recorded in accomplishing the work performed.
5. Objectively assess accomplishments at the work performance level.
6. Analyze significant variances from the plan, forecast impacts, and prepare an estimate at completion based on performance to date and work to be performed.
7. Use Performance Based information in the company's management processes.

C.2.2 **Performance Measurement Baseline (PMB)**

Contractor and BARDA shall mutually agree upon cost, schedule and technical plan baselines. These baselines shall be the basis for monitoring and reporting progress throughout the life of the contract.

C.2.3 **Integrated Baseline Review (IBR)**

The Contractor shall submit a plan for an Integrated Baseline Review to occur within 90 days of contract award. At the IBR, the Contractor and BARDA shall mutually agree upon cost, schedule and technical plan baseline (Performance Measurement Baseline). This baseline shall be the basis for monitoring and reporting progress throughout the life of the contract. The IBR is conducted to provide a mutual understanding of the inherent risks in Contractor's performance plans and the underlying management control systems, and it shall formulate a plan to handle these risks.

In the IBR, the Contractor shall:

- Demonstrate that there is a logical sequence of effort consistent with the contract schedule;
- Demonstrate the validity of the allocated cost accounts and budgets, both in terms of total resources and scheduling;
- Support BARDA's technical assessment of the performance measurement methodologies and variance analysis reporting thresholds that the Contractor is using to measure progress;
- Support BARDA's technical assessment of quality metrics;
- Verify that the cost, schedule, and technical plans are integrated. (The technical content of control accounts and work packages is consistent with the contract scope of work, the WBS and the WBS dictionary).

C.2.4 **Contract Performance Report (CPR)**

The Contractor shall deliver a Contract Performance Report on a monthly basis consistent with the instruction in Department of Defense Data Item Description (DID) DI-MGMT-81466A. Contractor shall provide Format 1, Format 3 and Format 5 only. Format 1 will be reported at the Work Breakdown Structure level agreed to by BARDA and the Contractor. Contractor shall provide preliminary CPR on the 15th day after end of Contractor reporting period and final CPR on the 20th day. EV Variance thresholds will be negotiated with the Contractor post-award but for planning purposes will likely be (+/- 10%).

C.2.5 **Integrated Master Schedule**

The Contractor shall deliver a program level Integrated Master Schedule (IMS) that rolls up all time-phased WBS elements down to the activity level. This IMS shall include the dependencies that exist between tasks.
The Contractor shall provide monthly delivery of the IMS status with performance data and shall include actual start/finish and projected start/finish dates. The status schedule shall be delivered 5 days after reporting month end.

C.2.6 **Work Breakdown Structure**

Work Breakdown Structures (WBS) shall be discernable and consistent. For example, BARDA may require the Contractor to furnish WBS data at the cost account level or at the work package level or at a lower level if there is significant complexity and risk associated with the task. Work Breakdown Structures shall be product and/or deliverable based where possible. BARDA encourages the use of MIL-HNDBK-881 as guidance.

The Contractor's baseline schedule shall have each task (activity) aligned to its corresponding WBS identification. The WBS identification shall be visible in its own unique field in the project schedule.

C.2.7 **Risk Management Plan**

The Contractor shall develop a risk management plan highlighting potential problems and/or issues that may arise during the life of the contract, their impact on cost, performance and timelines, and appropriate remediation plans. This plan shall reference relevant WBS elements, where appropriate.

ARTICLE C.3. REPORTING REQUIREMENTS

In addition to those reports required by other terms of this contract, the Contractor shall submit to the Contracting Officer and the Project Officer/COTR technical progress reports covering the work accomplished during each reporting period on a periodic basis as established by the Project Officer/COTR. These reports are subject to the technical inspection and requests for clarification by the Project Officer/COTR. These reports shall be brief and factual and prepared in accordance with the following format:

I. Technical Progress Reports: On the fifteenth of each month for the previous calendar month, the Contractor shall submit a report to the Project Officer/COTR and the Contracting Officer. The format and type of Technical Progress Report and Executive Summary will be provided by the Project Officer/COTR. Technical Progress Reports will include project timelines, milestones and summaries of product manufacturing, testing and clinical evaluation. A Technical Progress Report will not be required for the periods when a Final Report is due. The Contractor shall submit one copy of the Technical Progress Report electronically via e-mail. Any attachments to the e-mail report shall be submitted in Microsoft Word, Excel, PowerPoint, Microsoft Project and/or Adobe Acrobat PDF files. Such reports shall include the following specific information:

   A. Title page containing Technical Progress Report, the contract number and title, the period of performance or milestone being reported, the Contractor's name, address, and other contact information, the author(s), and the date of submission;

   B. Introduction/Background - An introduction covering the purpose and scope of the contract effort;

   C. Progress - The report shall detail, document, and summarize the results of work performed, test results, and milestones achieved during the period covered. Also to be included is a summary of work planned for the next reporting period including overall progress towards obtaining FDA approvals and licensure on new influenza vaccine(s);

   D. Issues - Issues resolved, new issues and outstanding issues are enumerated with options and recommendations for resolution. An explanation of any difference between planned progress and actual progress, why the differences have occurred, and, if project activity is delinquent, then what corrective steps are planned. Revised timelines are provided.

   E. Invoices – Summary of any invoices submitted during the reporting period.

   F. Action Items – Summary table of activities or tasks to be accomplished by a certain date and by whom.

   G. Distribution List – A list of persons receiving the Technical Progress report

   H. Attachments – Results on the project are provided as attachments

III. The Executive Summary, which shall accompany each Technical Progress Report, will be formatted in Microsoft Power Point presentations and include the following:

   A. Title page containing Executive Title, the contract number and title, the period of performance or milestone being reported, the Contractor's name and the date of submission;

   B. Project Progress presented as milestone events, test results, tasks and other activities achieved during the reporting period as talking point bullets;

   C. Project Issues presented headings and each item as a talking point bullet.

IV. Final Reports – The Contractor shall submit a Draft Final Report for the Base Period and Option Period One to the Project Officer/COTR and Contracting Officer within 45 calendar days prior to the contract expiration date. The Project Officer/COTR will review the draft report and provide the Contracting Officer with comments within 15 calendar days after receipt. The Final Report shall be corrected by the Contractor, if necessary and the final version delivered by the expiration date of the contract. The Contractor shall submit a comprehensive Final Report for the Base Period and Option Period One that shall detail, document and summarize the results of the entire contract work. The report shall explain comprehensively the results achieved.

SECTION D – PACKAGING, MARKING AND SHIPPING

ARTICLE D.1. SHIPPING

I. Method of Delivery

Unless otherwise specified by the Contracting Officer or the Project Officer/COTR, delivery of items, to be furnished to the Government under this contract (including invoices), shall be made by first class mail. All deliverables shall be marked with the contract number and Contractor name.

For delivery of the bulk vaccines under Optional CLIN 0015, the Contractor shall provide the Contracting Officer or the Project Officer/COTR with the estimated date of final QC release of the bulk vaccines. Within 30 days post-final release of the vaccine by the Contractor, the Contracting Officer or the Project Officer/COTR will provide delivery instructions to the Contractor.

II. Addressees – For all contract deliverables.

Project Officer/COTR
HHS/OS/ASPR/BARDA
330 Independence Avenue, SW
Room G640
Washington, D.C. 20201

Contracting Officer
HHS/OS/ASPR/AMCG
330 Independence Avenue, SW
Room G640
Washington, D.C. 20201

SECTION E – INSPECTION AND ACCEPTANCE

The Contracting Officer or the duly authorized representative (who for the purposes of this contract will be the Project Officer/COTR) will perform inspection and acceptance of materials and services to be provided under the contract. The contract will identify who will perform inspections and where the inspections will be performed. Acceptance may be presumed unless otherwise indicated in writing by the Contracting Officer or the duly authorized representative within 30 days of receipt.

Should the Government exercise Optional CLIN 0015, pursuant to FAR 52.246-16, risk of loss or damage to materials under Optional CLIN 0015 of this contract, shall pass to the Government upon the Government's acceptance of materials delivered to the destination provided by the Contracting Officer pursuant to D.1. of this contract. Government acceptance of materials under Optional CLIN 0015 shall occur after inspection pursuant to FAR 52.246-3 (except to the extent provided in FAR 52.246-16(c) regarding nonconforming materials), with written documentation for acceptance provided by the Contracting Officer to the Contractor as promptly as practicable after delivery but not later than 30 days of receipt.

The following clause is incorporated by reference with the same force and effect as if it were given in full text.

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

FAR Clause 52.246-9, Inspection of Research and Development (Short Form) (April 1984)

SECTION F – DELIVERIES OR PERFORMANCE

ARTICLE F.1. PERIOD OF PERFORMANCE

The period of performance for the Base Period (CLINs 0001 through 0010) shall be thirty-six (36) months from the effective date of contract award. This contract contains an option period. The option, if exercised, could potentially increase the period of performance an additional twenty-four (24) months. The option will be exercised in accordance with FAR Clause 52.217-9, Option to Extend the Term of the Contract (March 2000).

PERIOD	PERFORMANCE PERIOD
Option Period One	Thirty Six (36) months after the effective date of the contract through sixty (60) months after the effective date of the contract.

ARTICLE F.2. CONTRACT DELIVERABLES / TECHNICAL REPORT DISTRIBUTION

The items specified below as described in the Reporting Requirements in SECTION C and ARTICLE G.5. of this contract, will be required to be delivered F.O.B. Destination as set forth in FAR 52.247-35, F.O.B. Destination, Within Consignees Premises (April 1984) and in accordance with and by the dates specified below and any shipping specifications stated in SECTION D of this contract:

A. The following contract deliverables and technical reports are required for the Base Period of this contract.

CLIN	Deliverable	Quantity	Due Date
0001	**Product Development Plan** (Milestone 1)	Original – C.O. 2 Copies – P.O. 1 Electronic Copy – P.O.	Within Three (3) months after contract award.
0002	**Clinical Development and Regulatory Plan** (Milestone 2)	Original – C.O. 2 Copies – P.O. 1 Electronic Copy – P.O.	Within Three (3) months after contract award.
0003	**Manufacturing Facility Plan** (Milestone 3)	Original – C.O. 2 Copies – P.O. 1 Electronic Copy – P.O.	Within Nine (9) months after contract award.
0004	**Feasibility Plan** (Milestone 4)	Original – C.O. 2 Copies – P.O. 1 Electronic Copy – P.O.	Within Twelve (12) months after contract award.
0005A	**Contractor Defined Milestones** (Milestone 5A)	Original – C.O. 2 Copies – P.O. 1 Electronic Copy – P.O.	Within thirty-six (36) months after contract award.
0005B	**Contractor Defined Milestones** (Milestone 5B)	Original – C.O. 2 Copies – P.O. 1 Electronic Copy – P.O.	Within thirty-six (36) months after contract award.
0006	**Draft Security Plan**	Original – C.O. 2 Copies – P.O. 1 Electronic Copy – P.O.	Within thirty (30) days after contract award.
0007	**Final Security Plan**	Original – C.O. 2 Copies – P.O. 1 Electronic Copy – P.O.	Within thirty (30) days after USG's final comments.
0008	**Technical Progress Reports (Including EVM) and Executive Summary**	Original – C.O. 2 Copies – P.O. 1 Electronic Copy – P.O.	Due on/before the 15th of the month for the previous calendar month. See ARTICLE C.2. Not due when Final Report is due.
N/A	**Contract Financial Report**	Original – C.O. 2 Copies – P.O. 1 Electronic Copy – P.O.	Due on a quarterly basis on/before the 15th of the month. Not due when Final Report is due. See ARTICLE G.5.
0009	**Draft Final Report**	Original – C.O. 2 Copies – P.O. 1 Electronic Copy – P.O.	Due 45 days prior to the expiration date of the contract.
0010	**Final Report**	Original – C.O. 2 Copies – P.O.	Due on/before the expiration date of the contract.

		1 Electronic Copy – P.O.	

B. The following contract deliverables and technical reports are required for Option Period One of this contract.

CLIN	Deliverable	Quantity	Due Date
0011A	**Remaining Contractor Defined Milestones - Recombinant Seasonal Influenza Vaccine**	Original – C.O. 2 Copies – P.O. 1 Electronic Copy – P.O.	Within twenty-four (24) months after option period one award.
0011B	**Remaining Contractor Defined Milestones - Recombinant Pandemic Influenza Vaccine**	Original – C.O. 2 Copies – P.O. 1 Electronic Copy – P.O.	Within twenty-four (24) months after option period one award.
00012	**Technical Progress Reports (Including EVM) and Executive Summary**	Original – C.O. 2 Copies – P.O. 1 Electronic Copy – P.O.	Due on/before the 15th of the month for the previous calendar month. See ARTICLE C.2. Not due when Final Report is due.
N/A	**Contract Financial Report**	Original – C.O. 2 Copies – P.O. 1 Electronic Copy – P.O.	Due on a quarterly basis on/before the 15th of the month. Not due when Final Report is due. See ARTICLE G.5.
0013	**Draft Final Report**	Original – C.O. 2 Copies – P.O. 1 Electronic Copy – P.O.	Due 45 days prior to the expiration date of the contract.
0014	**Final Report**	Original – C.O. 2 Copies – P.O. 1 Electronic Copy – P.O.	Due on/before the expiration date of the contract.

C. The following contract deliverables are required for Optional CLIN 0015 of this contract.

1. The funded quantity, based on the exercise of optional CLIN 0015, shall be delivered to a location(s) to be designated by USG. The funded quantity by the exercise of the optional CLIN 0015 must be delivered to a location(s) to be designated by USG within a timeframe not to exceed six (6) months after the optional CLIN is exercised.

2. A FDA approval/licensure letter for the recombinant seasonal and pandemic influenza vaccine or copies of the Emergency Use Authorizations (EUA).

3. Copies of all FDA inspection reports, including Form 483, for all aspects of final finished product manufacturing and any cGMP inspection reports and copies of correspondence with FDA.

ARTICLE F.3. CLAUSES INCORPORATED BY REFERENCE, FAR 52.252-2 (FEBRUARY 1998)

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. Also, the full text of a clause may be accessed electronically at this address: http://www.acquisition.gov/comp/far/index.html

FAR CLAUSE 52.242-15, STOP WORK ORDER (AUG 1989) with ALTERNATE I (APR 1984)

SECTION G – CONTRACT ADMINISTRATION DATA

ARTICLE G.1. CONTRACTING OFFICER

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

2) The Contracting Officer is the only person with 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 any costs incurred during the performance of this contract; (5) obligate funds into or deobligate funds from the contract; or (6) otherwise change any terms and conditions of this contract.

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

ARTICLE G.2. PROJECT OFFICER / CONTRACTING OFFICER'S TECHNICAL REPRESENTATIVE (COTR)

The Government's Project Officer / COTR will represent the Government for the purpose of this contract.

Tanima Sinha

The Project Officer / COTR is responsible for: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) ensure the Contractor meets the technical requirements under the contract by the delivery date(s) and/or within the period of performance; (3) ensure the Contractor performs within the price or estimated cost stated in the contract; (4) interpreting the statement of work and any other technical performance requirements; (5) performing technical evaluation as required; (6) performing technical inspections and acceptances required by this contract; (7) assisting in the resolution of technical problems encountered during performance; and (8) review invoices submitted by the Contractor.

The Government may unilaterally change its Project Officer / COTR designation.

ARTICLE G.3. 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 individuals are considered to be essential to the work being performed hereunder:

NAME	TITLE
Gale Smith, Ph.D.	Principal Investigator
Denise Courbron, MS, PMP	Program Manager
John W. Madsen, Ph.D.	Process & Manufacturing
Steven Pincus, Ph.D.	Analytical & Quality Operations
TBD	Vice President Clinical Development
TBD	Regulatory Affairs
Penny Hylton, Ph.D.	Quality Assurance

ARTICLE G.4. INVOICE SUBMISSION/CONTRACT FINANCING REQUEST

Invoice/Financing Request instructions are attached and made part of this contract. The Contractor shall follow the attached instructions and submission procedures to meet the requirements of a "proper invoice" pursuant to FAR Subpart 32.9, Prompt Payment. All invoices shall include the appropriate documentation to support the amounts claimed/billed. All costs/prices shall be identified by CLIN. The Contractor shall submit an original and one copy of each invoice to the address shown below:

HHS/OS/ASPR/AMCG
330 Independence Avenue, SW, Room G640
Washington, DC 20201
Attn: RoseMary Mann, Contracting Officer
Contract No. HHSO100201100012C

ARTICLE G.5. CONTRACT FINANCIAL REPORT

a. Financial reports on the attached form, Financial Report of Individual Project/Contract (Attachment 2), shall be submitted by the Contractor in accordance with the instructions, which accompany the form, no later than the 15th working day after the close of the reporting period. The line entries for subdivisions of work and elements of cost (expenditure categories) which shall be reported within the total contract are discussed in paragraph e., below. Subsequent changes and/or additions in the line entries shall be made in writing. Financial reports shall be submitted by the Contractor to the address specified in Block 7 on the face page of the contract.

b. Unless otherwise stated in that part of the instructions entitled, "Preparation Instructions", all columns A through J shall be completed for each report submitted.

c. The first financial report shall cover the period consisting of the FIRST FULL THREE CALENDAR MONTHS following the date of the contract, in addition to any fractional part of the initial month. Thereafter, reports will be on a **quarterly** basis.

d. The Contracting Officer may require the Contractor to submit detailed support for costs contained in one or more interim financial reports. This clause does not supersede the record retention requirements in FAR Part 4.7.

e. The listing of expenditure categories to be reported is incorporated within Attachment 2 entitled, "Financial Report of Individual Project/Contract", located in SECTION J and made a part of this contract.

f. The financial report must be in compliance with EVMS requirements and the format shall be approved by the Government and include all negotiated budget elements.

g. The Government may unilaterally revise the expenditure categories to reflect the allotment of additional funds.

ARTICLE G.6. INDIRECT COST RATES

Profit making organizations will negotiate provisional and/or final indirect cost rates with their cognizant Government Agency. The Contractor shall bill in accordance with the indirect cost rates as indicated in the Contractor's Final Proposal dated February 04, 2011.

The indirect cost rates are as follows:

- Fringe Benefits - 43%
- Overhead – 81.7%
- General and Administrative (G&A) on total costs – 12%
- General and Administrative (G&A) on subcontractors – 1.5%

The indirect cost rates shall not exceed the ceiling rates and the Government is not obligated to pay any amounts that are in excess of these ceiling rates.

ARTICLE G.7. 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, "Contractor's Guide for Control of Government Property", which is incorporated into this contract by reference. This document can be accessed at:

http://www.hhs.gov/hhsmanuals/logisticsmanual/Appendix%20Q_HHS%20Contracting%20Guide.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. A copy of this publication is available upon request to the Contracts Property Administrator.

b. Notwithstanding the provisions outlined in the HHS Publication, "Contractor's Guide for Control of Government Property", which is incorporated in this contract in paragraph a. above, the Contractor shall use the form entitled, "Report of Government Owned, Contractor Held Property" (Attachment 3) for submitting summary reports or for performing annual inventories required under this contract, as directed by the Contracting Officer or his/her designee. This form is included as an attachment in SECTION J of this contract.

ARTICLE G.8. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

Interim and final evaluations of Contractor performance will be conducted on this contract in accordance with FAR 42.15. The final performance evaluation will be prepared at the time of completion of work. Interim and final evaluations will be submitted to the Contractor as soon as practicable after completion of the evaluation. The Contractor will be permitted 30 days to review the document and to submit additional information or a rebutting statement. 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.

SECTION H – SPECIAL CONTRACT REQUIREMENTS

ARTICLE H.1. HUMAN SUBJECTS

Research involving human subjects shall not be conducted under this contract until the protocol developed in Phase I has been approved by the Department of Health and Human Services, 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.2. PROTECTION OF HUMAN SUBJECTS

a.) No contract involving human subjects research shall be awarded until acceptable assurance has been given that the project or activity will be subject to initial and continuing review by an appropriate institutional review committee (s) as described in 45 CFR Part 46. Contracts involving human subjects will not be awarded to an individual unless the individual is affiliated with or sponsored by an institution that has an Office for Human Research Protections (OHRP) approved assurance of compliance in place and will assume responsibility for safeguarding the human subjects involved. The OHRP web site is: http://www.hhs.gov/ohrp. 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 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. Nothing in this contract shall be deemed 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 performance of this contract, the Contracting Officer determines, in consultation with the 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 such noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing.

d) 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 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 Health and Human Services Human Subject Assurances.

ARTICLE H.3. 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.4. RESEARCH INVOLVING RECOMBINANT DNA MOLECULES

All research involving Recombinant DNA Molecules shall be conducted in accordance with the NIH Guidelines for Research Involving Recombinant DNA Molecules (http://oba.od.nih.gov/rdna/nih_guidelines_oba.html)and the September 24, 2007 Notice, "Reminder of NIH Policy for Enhancing the Science, Safety, and Ethics of Recombinant DNA Research" (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-096.html) (and any subsequent revisions to the Guide Notice) which stipulates biosafety and containment measures for recombinant DNA research and delineates critical, ethical principles and key safety reporting requirements for human gene transfer research (See Appendix M of the Guidelines). These guidelines apply to both basic and clinical research studies.

The Recombinant DNA Advisory Committee (RAC) is charged with the safety of manipulation of genetic material through the use of recombinant DNA techniques. Prior to beginning any clinical trials involving the transfer of recombinant DNA to humans, the trial must be registered with the RAC. If this contract involves new protocols that contain unique and//or novel issues, the RAC must discuss them in a public forum and then the Institutional Biosafety Committee (IBC), the Institutional Review Board (IRB), and the Project Officer and Contracting Officer must approve the protocol prior to the start of the research.

Failure to comply with these requirements may result in suspension, limitation, or termination of the contract for any work related to Recombinant DNA Research or a requirement for Contracting Officer prior approval of any or all Recombinant DNA projects under this contract. This includes the requirements of the Standing Institutional Biosafety Committee (IBC) (See http://oba.od.nih.gov/rdna_ibc/ibc.html)

As specified in Appendix M-1-C-4 of the NIH Guidelines, any serious adverse event must be reported immediately to the IRB, the IBC, the Office for Human Research Protections (if applicable), and the NIH Office for Biotechnology Activities (OBA), followed by the filing of a written report with each office/group and copies to the Project Officer and Contracting Officer. (http://oba.od.nih.gov/oba/rac/Guidelines/APPENDIX_M.htm#_Toc7255846).

ARTICLE H.5. NEEDLE EXCHANGE

Pursuant to current HHS annual appropriations act, 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.6. RESTRICTION ON EMPLOYMENT OF UNAUTHORIZED ALIEN WORKERS

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

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

ARTICLE H.7. ANIMAL WELFARE

Notice to Contractors of Requirements for Adequate Assurance of Protection of Vertebrate Animal Subjects

The PHS Policy on Humane Care and Use of Laboratory Animals requires that applicant organizations proposing to use vertebrate animals file a written Animal Welfare Assurance with the Office for Laboratory Animal Welfare (OLAW), establishing appropriate policies and procedures to ensure the humane care and use of live vertebrate animals involved in research activities supported by the PHS. The PHS policy stipulates that an applicant organization, whether domestic or foreign, bears responsibility for the humane care and use of animals in PHS-supported research activities. Also, the PHS policy defines "animal" as "any live, vertebrate animal used, or intended for use, in research, research training, experimentation, biological testing or for related purposes". This Policy implements and supplements the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training and requires that institutions use the Guide for the Care and use of Laboratory Animals as a basis for developing and implementing an institutional animal care and use program. This Policy does not affect applicable State or local laws or regulations that impose more stringent standards for the care and use of laboratory animals. All institutions are required to comply, as applicable, with the Animal Welfare Act as amended (7 USC 2131 et.seq.) and other Federal statutes and regulations relating to animals. These documents are available from the Office of Laboratory Animal Welfare, National Institutes of Health, Bethesda, MD 20892, (301) 496-7163. See http://grants.nih.gov/grants/olaw/olaw.htm .

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

Care of Live Vertebrate Animals

1. Before undertaking performance of any contract involving research on live, vertebrate animals, the Contractor shall register with the Secretary of Agriculture of the United States in accordance with 7 U.S.C. 2316 and 9 CFR Section 2.30. The Contractor shall furnish evidence of such registration to the Contracting officer.

2. The Contractor shall acquire animals used in research from a dealer licensed by the Secretary of Agriculture under 7 U.S.C. 2131-2157 and 9 CFR Sections 2.1-2.11, or from a source that is exempt from licensing under those sections.

3. The Contractor agrees that the care and use of any live, vertebrate animals used or intended for use in the performance of this contract will conform with the PHS Policy on Humane Care and Use of Laboratory Animals, the current Animal Welfare Assurance, the Guide for the Care and Use of Laboratory Animals prepared by the Institute of Laboratory Animal Resources 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 1-3). In case of conflict between standards, the more stringent standard shall be used.

4. 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/or standards stated in paragraphs (1) through (3) 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 Contractor's with approved Public Health Service Animal Welfare Assurances.

5. The Contractor may request registration of its facility and a current listing of licensed dealers from the Animal Care Sector Office of the Animal and Plant Health Inspection Service (APHIS), USDA, for the sector 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:

Animal Care Staff USDA/APHIS 4700 River Road, Unit 84, Riverdale, MD 20737, (301) 734-4980. Contractors proposing research that involves live, vertebrate animals will be contacted by OLAW and given detailed instructions on filing a written Animal Welfare Assurance with the PHS. Contractors are encouraged to visit the OLAW website at http://grants.nih.gov/grants/olaw/olaw.htm for additional information. OLAW may be contacted at the National Institutes of Health at (301) 594-2289.

Approval of Required Assurance by OLAW

Under governing regulations, federal funds which are administered by the HHS shall not be expended by the Contractor for research involving live, vertebrate animals nor shall live vertebrate animals be involved in research activities by the Contractor under this award unless a satisfactory assurance of compliance with 7 U.S.C. 2316 and 9 CFR Sections 2.25-2.28 is submitted within 30 days of the date of this award and approved by the Office of Laboratory Animal Welfare (OLAW). Each performance site (if any) must also assure compliance with 7 U.S.C. 2316 and 9 CFR Sections 2.25-2.28 with the following restriction: Only activities which do not directly involve live vertebrate animals (i.e., are clearly severable and independent from those activities that do involve live vertebrate animals) may be conducted by the Contractor or individual performance sites pending OLAW approval of their respective assurance of compliance with 7 U.S.C. 2316 and 9 CFR Sections 2.25-2.28.

ARTICLE H.8. OPTION PROVISION

Unless the Government exercises its option pursuant to the Option Clause set forth in ARTICLE I.3., the contract will consist only of the Base Period of the Statement of Work as defined in Sections C and F of the contract. Pursuant to FAR Clause 52.217-9, Option to Extend the Term of the Contract set forth in ARTICLE I.3. of this contract, the Government may, by unilateral contract modification, require the Contractor to perform additional options set forth in the Statement of Work and also defined in Sections C and F of the contract. If the Government exercises this option, notice must be given at least 30 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 Option Prices as specified in Article B.2. of this contract.

ARTICLE H.9. INSTITUTIONAL RESPONSIBILITY REGARDING CONFLICTING INTERESTS OF INVESTIGATORS

The Contractor shall comply with the requirements of 45 CFR Part 94, Responsible Prospective Contractors, which promotes objectivity in research by establishing standards to ensure that investigators (defined as the principal investigator and any other person who is responsible for the design, conduct or reporting of research funded under HHS contracts) will not be biased by any conflicting financial interest. 45 CFR Part 94 is available at the following Web site: http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr;sid=9f130b6d2d48bb73803ca91ce943be3a;rgn=div5;view=text;node=45%3A1.0.1.1.53;idno=45;cc=ecfr

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

a. Maintain a written, enforceable policy on conflict of interest that complies with 45 CFR Part 94 and inform each investigator of the policy, the investigator's reporting responsibilities and the applicable regulations. The Contractor must take reasonable steps to ensure that investigators working as collaborators or subcontractors comply with the regulations.

b. Designate an official(s) to solicit and review financial disclosure statements from each investigator participating in HHS-funded research. Based on established guidelines consistent with the regulations, the designated official(s) must determine whether a conflict of interest exists, and if so, determine what actions shall be taken to manage, reduce or eliminate such conflict. A conflict of interest exists when the designated official(s) reasonably determines that a *Significant Financial Interest* could directly and significantly affect the design, conduct or reporting of the HHS-funded research. The Contractor may require the management of other conflicting financial interests in addition to those described in this paragraph, as it deems appropriate. Examples of conditions or restrictions that might be imposed to manage actual or potential conflicts of interests are included in 45 CFR Part 94, under Management of Conflicting Interests.

c. Require all financial disclosures to be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.

d. Maintain records, identifiable to each award, of all financial disclosures and all actions taken by the Contractor with respect to each conflicting interest 3 years after final payment or, where applicable, for the other time periods specified in 48 CFR Part 4, subpart 4.7, Contract Records Retention.

e. Establish adequate enforcement mechanisms and provide for sanctions where appropriate.

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

If the failure of an investigator to comply with the conflict of interest policy has biased the design, conduct or reporting of the HHS-funded research, the Contractor must promptly notify the Contracting Officer of the corrective action taken or to be taken. The Contracting Officer will take appropriate action or refer the matter to the Contractor for further action, which may include directions to the Contractor on how to maintain appropriate objectivity in the funded research. If corrective action has not been taken or is not appropriate and the contract cannot be performed, the Government reserves the right to terminate the contract for default in accordance with FAR 52.249-6, Termination (Cost-Reimbursement) (May 2004).

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

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

ARTICLE H.10. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

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

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

ARTICLE H.11. POSSESSION USE AND TRANSFER OF SELECT BIOLOGICAL AGENTS OR TOXINS

The Contractor shall not conduct work involving select agents or toxins 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 Select Agents 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.aphis.usda.gov/programs/ag_selectagent/), as required, before using HHS funds for work involving a *Select Agent or Toxin*. No HHS 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 HHS funds for any work directly involving a *Select Agent or Toxin*, the foreign institution must provide information satisfactory to the HHS 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 inspection of the foreign laboratory facility by HHS representatives. During this inspection, 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 Agents and procedures for ensuring that only approved and appropriate individuals, in accordance with institution procedures, will have access to the Select Agents 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. No HHS funds can be used for work involving a *Select Agent or Toxin* at a foreign institution without approval from the Contracting Officer.

Listings of HHS 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/

Listings of USDA select agents and toxins as well as information about the registration process for domestic institutions are available on the APHIS/USDA website at: http://www.aphis.usda.gov/programs/ag_selectagent/.

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

ARTICLE H.12. 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.13. NOTICE PRIOR TO PUBLICATION

The Contractor shall not release any reports, manuscripts, press releases, or abstracts about the work being performed under this contract without written notice in advance to the Government, for additional information see HHSAR 352.227-70.

ARTICLE H.14. IDENTIFICATION AND DISPOSITION OF DATA

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

ARTICLE H.15. ACKNOWLEDGEMENT OF FEDERAL FUNDING

A. Pursuant to the current HHS annual appropriations act, Contractors funded with Federal dollars, in whole or in part, acknowledges Federal funding when issuing statements, press releases, request for proposals, bid solicitations and other documents. Contractors are required to state (1) the percentage and dollar amounts of the total program or project costs financed with Federal money, and (2) the percentage and dollar amount of the total costs financed by nongovernmental sources.

This requirement is in addition to the continuing requirement to provide an acknowledgment of support and disclaimer on any publication reporting the results of a contract funded activity.

B. 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 Department of Health and Human Services (HHS), Office of the Assistant Secretary for Preparedness and Response (ASPR), Biomedical Advanced Research and Development Authority (BARDA), whenever publicizing the work under this contract in any media by including an acknowledgement substantially as follows:

"This project has been funded in whole or in part with Federal funds from the Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, Department of Health and Human Services, under Contract No. HHSO100201100012C.

C. Press Releases

Pursuant to the current HHS annual appropriations act, 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.16. MANUFACTURING STANDARDS

The Current Good Manufacturing Practice Regulations (cGMP) (21 CFR Parts 210-211) will be the standard to be applied for manufacturing, processing and packing of this therapeutic product.

If at any time during the life of the contract, the Contractor fails to comply with cGMP in the manufacturing, processing and packaging of this therapeutic product and such failure results in a material adverse effect on the safety, purity or potency of this therapeutic product (a material failure) as identified by CBER and CDER, the Contractor shall have thirty (30) calendar days from the time such material failure is identified to cure such material failure. If the Contractor fails to take such an action within the thirty (30) calendar day period, then the contract may be terminated.

PART II – CONTRACT CLAUSES

SECTION I – CONTRACT CLAUSES

ARTICLE I.1. GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT - FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)

This contract incorporates the following clauses by reference, with the same force and effect as if they were given in full text. Upon request the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this address: http://www.acquisition.gov/comp/far/index.html
http://www.hhs.gov/oamp/policies/hssar.doc

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

FAR CLAUSE NO.	DATE	TITLE
52.202-1	*Jul 2004*	*Definitions (Over $100,000)*
52.203-3	*Apr 1984*	*Gratuities (Over $100,000)*
52.203-5	*Apr 1984*	*Covenant Against Contingent Fees (Over $100,000)*
52.203-6	*Sep 2006*	*Restrictions on Subcontractor Sales to the Government (Over $100,000)*
52.203-7	*Oct 2010*	*Anti-Kickback Procedures (Over $150,000)*
52.203-8	*Jan 1997*	*Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Over $100,000)*
52.203-10	*Jan 1997*	*Price or Fee Adjustment for Illegal or Improper Activity (Over $100,000)*
52.203-12	*Oct 2010*	*Limitation on Payments to Influence Certain Federal Transactions (Over $150,000)*
52.204-4	*Aug 2000*	*Printed or Copied Double-Sided on Recycled Paper (Over $100,000)*
52.204-7	*Apr 2008*	*Central Contractor Registration*
52.204-10	*Jul 2010*	*Reporting Executive Compensation and First-Tier Subcontract Awards ($25,000 or more)*
52.209-6	*Dec 2010*	*Protecting the Government's Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (Over $30,000)*
52.215-2	*Oct 2010*	*Audit and Records - Negotiation*
52.215-8	*Oct 1997*	*Order of Precedence - Uniform Contract Format*
52.215-10	*Oct 2010*	*Price Reduction for Defective Certified Cost or Pricing Data (Over $700,000)*
52.215-12	*Oct 2010*	*Subcontractor Certified Cost or Pricing Data (Over $700,000)*
52.215-14	*Oct 2010*	*Integrity of Unit Prices*
52.215-15	*Oct 2010*	*Pension Adjustments and Asset Reversions*
52.215-18	*Jul 2005*	*Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) other than Pensions*
52.215-19	*Oct 1997*	*Notification of Ownership Changes*
52.215-21	*Oct 2010*	*Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data - Modifications*
52.216-7	*Dec 2002*	*Allowable Cost and Payment*
52.216-8	*Mar 1997*	*Fixed Fee*
52.219-8	*Jan 2011*	*Utilization of Small Business Concerns (Over $150,000)*
52.219-9	*Jan 2011*	*Small Business Subcontracting Plan (Over $650,000, $1,500,000 for Construction)*
52.219-16	*Jan 1999*	*Liquidated Damages - Subcontracting Plan*
52.222-2	*Jul 1990*	*Payment for Overtime Premium (Over $100,000) (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	*Sep 2010*	*Equal Opportunity for Veterans (Over $100,000)*
52.222-36	*Oct 2010*	*Affirmative Action for Workers with Disabilities*
52.222-37	*Sep 2010*	*Employment Reports Veterans (Over $100,000)*
52.222-50	*Feb 2009*	*Combating Trafficking in Persons*
52.223-6	*May 2001*	*Drug-Free Workplace*
52.223-14	*Aug 2003*	*Toxic Chemical Release Reporting (Over $100,000)*
52.225-1	*Feb 2009*	*Buy American Act - 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	*Dec 2007*	*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	*Dec 2007*	*Rights in Data - General*
52.232-9	*Apr 1984*	*Limitation on Withholding of Payments*
52.232-17	*Oct 2010*	*Interest*
52.232-20	*Apr 1984*	*Limitation of Cost*
52.232-23	*Jan 1986*	*Assignment of Claims*
52.232-25	*Oct 2008*	*Prompt Payment, Alternate I (Feb 2002)*
52.232-33	*Oct 2003*	*Payment by Electronic Funds Transfer--Central Contractor Registration*
52.233-1	*Jul 2002*	*Disputes*
52.233-3	*Aug 1996*	*Protest After Award, Alternate I (Jun 1985)*
52.233-4	*Oct 2004*	*Applicable Law for Breach of Contract Claim*
52.242-1	*Apr 1984*	*Notice of Intent to Disallow Costs*
52.242-3	*May 2001*	*Penalties for Unallowable Costs (Over $700,000)*
52.242-4	*Jan 1997*	*Certification of Final Indirect Costs*
52.242-13	*Jul 1995*	*Bankruptcy (Over $150,000)*
52.243-2	*Aug 1987*	*Changes - Cost Reimbursement, Alternate V (Apr 1984)*
52.244-2	*Oct 2010*	*Subcontracts, Alternate I (June 2007)*
52.244-5	*Dec 1996*	*Competition in Subcontracting (Over $150,000)*
52.244-6	*Dec 2010*	*Subcontracts for Commercial Items*
52.245-1	*Aug 2010*	*Government Property*
52.245-9	*Aug 2010*	*Use and Charges*
52.246-23	*Feb 1997*	*Limitation of Liability (Over $150,000)*
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	*Jan 2006*	*Anti-Lobbying*
352.216-70	*Jan 2006*	*Additional Cost Principles*
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*

ARTICLE I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES

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

FAR Clauses **52.219-9, Small Business Subcontracting Plan** (January 2011), and **52.219-16, Liquidated Damages—Subcontracting Plan** (January 1999) are deleted in their entirety.

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.

a. 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/hotline/OIG_Hotline_Poster.pdf

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

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

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

"c) The total duration of this contract, including the exercise of Option Period One under this clause, shall not exceed 60 months.

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

"(c) Waiver of evaluation preference.....

[ ] Contractor elects to waive the evaluation preference."

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

b. 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 **352.270-4, Protection of Human Subjects** (January 2006).

(4) HHSAR Clause **352.270-5, Care of Laboratory Animals** (January 2006).

(5) HHSAR Clause **352.270-6, Restriction on Use of Human Subjects** (January 2006).

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

This contract incorporates the following clauses in full text.

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

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

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

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

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

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

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

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

(3) For long-term contracts—

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

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

(c) The Contractor shall re-represent its size status in accordance with the size standard in effect at the time of this re-representation that corresponds to the North American Industry Classification System (NAICS) code assigned to this contract. The small business size standard corresponding to this NAICS code can be found at:
http://www.naics.com/SizeStandards.htm#Manufacturing

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

(e) Except as provided in paragraph (g) of this clause, the Contractor shall make the re-representation required by paragraph (b) of this clause by validating or updating all its representations in the Online Representations and Certifications Application and its data in the Central Contractor Registration, as necessary, to ensure they reflect the Contractor's current status. The Contractor shall notify the contracting office in writing within the timeframes specified in paragraph (b) of this clause that the data have been validated or updated, and provide the date of the validation or update.

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

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

The Contractor represents that it [X] is, [ ] is not a small business concern under NAICS Code 325414 assigned to contract number HHSO100201100012C.

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

(g)(3) Notwithstanding paragraph (g)(1) of this clause, the contract may identify and specify the delivery of limited rights data or the Contracting Officer may require by written request the delivery of limited rights data that has been withheld or would otherwise be entitled to be withheld.. If delivery of that data is required, the Contractor shall affix the following "Limited Rights Notice" to the data and the Government will treat the data, subject to the provisions of paragraphs (e) and (f) of this clause, in accordance with the notice:

Limited Rights Notice (December 2007)

(a) These data are submitted with limited rights under Government Contract No. HHSO100201100012C . These data may be reproduced and used by the Government with the express limitation that they will not, without written permission of the Contractor, be used for purposes of manufacture nor disclosed outside the Government; except that the Government may disclose these data outside the Government for the following purposes, if any; provided that the Government makes such disclosure subject to prohibition against further use and disclosure:

(i) Use (except for manufacture) by support service Contractors.

(b) This notice shall be marked on any reproduction of these data, in whole or in part.

PART III – LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J – LIST OF ATTACHMENTS

The following documents are attached and incorporated into this contract:

Attachment No.	Title	
Attachment 1:	Invoice/Financing Request Instructions for – Cost-Reimbursement Type Contracts (4 pages)	See Attachment Section at the end of this contract.
Attachment 2:	Financial Report of Individual Project/Contract and Instructions (4 pages)	**Provided as a separate document.**
Attachment 3:	Report of Government Owned Contractor Held Property (1 page)	**Provided as a separate document.**
Attachment 4:	Contractor Defined Milestones (February 4, 2011, 5 pages)	**Provided as a separate document.**

PART IV – REPRESENTATIONS AND INSTRUCTIONS

SECTION K – REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

The following documents are incorporated by reference in this contract:

Annual Representations and Certifications completed and located at the Online Representations and Certifications Application (ORCA) website. [This includes the changes, if any, identified in paragraph (b) of the FAR provision 52.204-8, Annual Representations and Certifications, contained in the contractor's proposal.]

ATTACHMENT 1

INVOICE/FINANCING REQUEST INSTRUCTIONS FOR COST-REIMBURSEMENT TYPE CONTRACTS

General: The Contractor shall submit claims for reimbursement in the manner and format described herein and as illustrated in the sample invoice/financing request.

Format: Standard Form 1034, "Public Voucher for Purchases and Services Other Than Personal," and Standard Form 1035, "Public Voucher for Purchases and Services Other Than Personal-- Continuation Sheet," or reproduced copies of such forms marked ORIGINAL shall be used to submit claims for reimbursement. In lieu of SF-1034 and SF-1035, claims may be submitted on the payee's letter-head or self-designed form provided that it contains the information shown on the sample invoice/financing request.

Number of Copies: As indicated in the Invoice Submission Clause in the contract.

Frequency: Invoices/financing requests submitted in accordance with the Payment Clause shall be submitted monthly unless otherwise authorized by the contracting officer.

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: (l) 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 amount and month(s) in which such costs were incurred shall be cited.

Contractor's Fiscal Year: Invoices/financing requests shall be prepared in such a manner that costs claimed can be identified with the Contractor's fiscal year.

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

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

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

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

(b) **Completion Invoice** — The completion invoice is submitted promptly upon completion of the work; but no later than one year from the contract completion date, or within 120 days after settlement of the final indirect cost rates covering the year in which this contract is physically complete (whichever date is later). The completion invoice shall be submitted 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 explanatory notes below. These notes are keyed to the entries on the sample invoice/financing request.

(a) **Designated Billing Office Name and Address** — Enter the designated billing office name and address, identified in the Invoice Submission Clause of the contract, on all copies of the invoice/financing request.

(b) **Invoice/Financing Request Number** — Insert the appropriate serial number of the invoice/financing request.

(c) **Date Invoice/Financing Request Prepared** — Insert the date the invoice/financing request is prepared.

(d) **Contract Number and Date** — Insert the contract number and the effective date of the contract.

(e) **Payee's Name and Address** — Show the Contractor's name (as it appears in the contract), correct address and the title and phone number of the responsible official to whom payment is to be sent. When an approved assignment has been made by the Contractor, or a different payee has been designated, then insert the name and address of the payee instead of the Contractor.

(f) **Total Estimated Cost of Contract** — Insert the total estimated cost of the contract, exclusive of fixed-fee. For incrementally funded contracts, enter the amount currently obligated and available for payment.

(g) **Total Fixed-Fee** — Insert the total fixed-fee (where applicable). For incrementally funded contracts, enter the amount currently obligated and available for payment.

(h) **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.

(i) **Amount Billed for Current Period** — Insert the amount billed for the major cost elements, adjustments, and adjusted amounts for the period.

(j) **Cumulative Amount from Inception** — Insert the cumulative amounts billed for the major cost elements and adjusted amounts claimed during this contract.

(k) **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.

(2) **Fringe Benefits** — List any fringe benefits applicable to direct labor and billed as a direct cost. Fringe benefits included in indirect costs shall not be identified here.

(3) **Accountable Personal Property** — Include permanent research equipment and general purpose equipment having a unit acquisition cost of $1,000 or more and having an expected service life of more than two years, and sensitive property regardless of cost (see the HHS *Contractor's Guide for Control of Government Property*). Show permanent research equipment separate from general purpose equipment. Prepare and attach Form HHS-565, "Report of Accountable Property," in accordance with the following instructions:

List each item for which reimbursement is requested. A reference shall be made to the following (as applicable):

- The item number for the specific piece of equipment listed in the Property Schedule.
- The COA letter and number, if the equipment is not covered by the Property Schedule.
- Be preceded by an asterisk (*) if the equipment is below the approval level.

Further itemization of invoices/financing requests shall only be required for items 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's advance understanding or in the COA letter, as well as the effort (i.e., number of hours, days, etc.) and rate being billed.

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

(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.

(l) **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.

(m) **Indirect Costs--Overhead** — Identify the cost base, indirect cost rate, and amount billed for each indirect cost category.

(n) **Fixed-Fee Earned** — Cite the formula or method of computation for the fixed-fee (if any). The fixed-fee must be claimed as provided for by the contract.

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

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

(q) **Grand Totals**

The contracting officer may require the Contractor to submit detailed support for costs claimed on one or more interim invoices/financing requests.

SAMPLE INVOICE/FINANCING REQUEST

(a) Billing Office Name and Address

DEPARTMENT OF HEALTH & HUMAN SERVICES
Assistant Secretary for Preparedness & Response
Biomedical Advanced Research Development Authority
330 Independence Avenue, S.W., Room G640
Washington, DC 20201

(b) Invoice/Financing Request No. _____

(c) Date Invoice Prepared _____

(d) Contract No. and Effective Date _____

(e) Payee's Name and Address

ABC CORPORATION
100 Main Street
Anywhere, U.S.A. zip code

(f) Total Estimated Cost of Contract _____

(g) Total Fixed Fee _____

Attention: Name, Title, and Phone Number of Official to Whom Payment is Sent

Contractor's Tax Identification Number (TIN): _____

(h) This invoice/financing request represents reimbursable costs from Aug. l, 1982 through Aug. 31, 1982

		(i) Amount Billed for Current Period	(j) Cumulative Amount From Inception
(k)	Direct Costs		
	(l) Direct Labor	$ 3,400	$ 6,800
	(2) Fringe Benefits	600	1,200
	(3) Accountable Personal Property (Attach Form HHS-565)		
	Permanent Research	3,000	6,000
	General Purpose	2,000	2,000
	(4) Materials and Supplies	2,000	4,000
	(5) Premium Pay	100	150
	(6) Consultant Fee-Dr. Jones 1 day @ 100 (COA #3)	100	100
	(7) Travel (Domestic)	200	200
	(Foreign)	200	200
	(8) Subcontract Costs	-0-	-0-
	(9) Other	-0-	-0-
	Total Direct Costs	$11,600	$20,650
(l)	Cost of Money (Factor) of (Appropriate Base)	2,400	3,600
(m)	Indirect Costs -- Overhead		
	_____% of Direct Labor or Other Base (Formula)	4,000	6,000
(n)	Fixed-Fee Earned (Formula)	700	1,400
(o)	Total Amount Claimed	$18,700	$31,650
(p)	Adjustments		
	Outstanding Suspensions		(1,700)
(q)	Grand Totals	$18,700	$29,950

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

_____ _____
Name of Official) (Title)

ATTACHMENT 2

Biomedical Advanced Research And Development Authority FINANCIAL REPORT OF INDIVIDUAL PROJECT/CONTRACT *Note: Complete this Form in Accordance with Accompanying Instructions.*	**Project Task:** Advanced Development of Recombinant Influenza Vaccine Products and Manufacturing Capabilities for Pandemic Preparedness	**RFP No.:** HHSO100201100012C	**Date of Report:**	**0990-0134** **0990-0131**
	Reporting Period:	**Contractor Name and Address:**		

Expenditure Category	Percentage of Effort/Hours		Cumulative Incurred Cost at End of Prior Period	Incurred Cost– Current Period	Cumulative Cost to Date (D + E)	Estimated Cost to Complete	Estimated Cost at Completion (F + G)	Negotiated Contract Amount	Variance (Over or Under) (I - H)
	Negotiated	Actual							
A	B	C	D	E	F	G	H	I	J

ATTACHMENT 2

INSTRUCTIONS FOR COMPLETING
"FINANCIAL REPORT OF INDIVIDUAL PROJECT/CONTRACT"

GENERAL INFORMATION

Purpose. The Financial Report of Individual Project/Contract is designed to: (1) provide a management tool for use by BARDA in monitoring the application of financial and personnel resources to the BARDA contracts; (2) provide contractors with financial and personnel management data which is usable in their management processes; (3) promptly indicate potential areas of contract underruns or overruns by making possible comparisons of actual performance and projections with prior estimates on individual elements of cost and personnel; and (4) obtain contractor's analysis of cause and effect of significant variations between actual and prior estimates of financial and personnel performance.

REPORTING REQUIREMENTS

Scope. The specific cost and personnel elements to be reported shall be established by mutual agreement prior to award. The Government may require the contractor to provide detailed documentation to support any element(s) on one or more financial reports.

Number of Copies and Mailing Address. An original and two (2) copies of the report(s) shall be sent to the contracting officer at the address shown on the face page of the contract, no later than 30 working days after the end of the period reported. However, the contract may provide for one of the copies to be sent directly to the Project Officer/COTR.

REPORTING STATISTICS

A modification which extends the period of performance of an existing contract will not require reporting on a separate Financial Report, except where it is determined by the contracting officer that separate reporting is necessary. Furthermore, when incrementally funded contracts are involved, each separate allotment is not considered a separate contract entity (only a funding action). Therefore, the statistics under incrementally funded contracts should be reported cumulatively from the inception of the contract through completion.

Definitions and Instructions for Completing Financial Report of Individual Project/Contract. For the purpose of establishing expenditure categories in Column A, the following definitions and instructions will be utilized. Each contract will specify the categories to be reported.

(1) **Key Personnel.** Include key personnel regardless of annual salary rates. All such individuals should be listed by names and job titles on a separate line including those whose salary is not directly charged to the contract but whose effort is directly associated with the contract. The listing must be kept up to date.

(2) **Personnel--Other.** List as one amount unless otherwise required by the contract.

(3) **Fringe Benefits.** Include allowances and services provided by the contractor to employees as compensation in addition to regular salaries and wages. If a fringe benefit rate(s) has been established identify the base, rate, and amount billed for each category. If a rate has not been established, the various fringe benefit costs may be required to be shown separately. Fringe benefits which are included in the indirect cost rate should not be shown here.

(4) **Accountable Personal Property.** Include nonexpendable personal property with an acquisition cost of $1,000 or more and with an expected useful life of two or more years, and sensitive items regardless of cost. Form HHS 565, "Report of Accountable Property," must accompany the contractor's public voucher (SF 1034/SF 1035) or this report if not previously submitted. See "Contractor's Guide for Control of Government Property."

(5) **Supplies.** Include the cost of supplies and material and equipment charged directly to the contract, but excludes the cost of nonexpendable equipment as defined in (4) above.

(6) **Inpatient Care.** Include costs associated with a subject while occupying a bed in a patient care setting. It normally includes both routine and ancillary costs.

(7) **Outpatient Care.** Include costs associated with a subject while not occupying a bed. It normally includes ancillary costs only.

(8) **Travel.** Include all direct costs of travel, including transportation, subsistence and miscellaneous expenses. Travel for staff and consultants shall be shown separately. Identify foreign and domestic travel separately. If required by the contract, the following information shall be submitted: (i) Name of traveler and purpose of trip; (ii) Place of departure, destination and return, including time and dates; and (iii) Total cost of trip.

(9) **Consultant Fee.** Include fees paid to consultant(s). Identify each consultant with effort expended, billing rate, and amount billed.

(10) **Premium Pay.** Include the amount of salaries and wages over and above the basic rate of pay.

(11) **Subcontracts.** List each subcontract by name and amount billed.

(12) **Other Costs.** Include any expenditure categories for which the Government does not require individual line item reporting. It may include some of the above categories.

(13) **Overhead/Indirect Costs.** Identify the cost base, indirect cost rate, and amount billed for each indirect cost category.

(14) **General and Administrative Expense.** Cite the rate and the base. In the case of nonprofit organizations, this item will usually be included in the indirect cost.

(15) **Fee.** Cite the fee earned, if any.

(16) **Total Costs to the Government.**

PREPARATION INSTRUCTIONS

These instructions are keyed to the Columns on the Financial Report.

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

Column B--Percentage of Effort/Hours Negotiated. Enter the percentage of effort or number of hours agreed to during contract negotiations for each labor category listed in Column A.

Column C--Percentage of Effort/Hours-Actual. Enter the cumulative percentage of effort or number of hours worked by each employee or group of employees listed in Column A.

Column D--Cumulative Incurred Cost at End of Prior Period. Enter the cumulative incurred costs up to the end of the prior reporting period. This column will be blank at the time of the submission of the initial report.

Column E--Incurred Cost-Current Period. Enter the costs which were incurred during the current period.

Column F--Cumulative Incurred Cost to Date. Enter the combined total of Columns D and E.

Column G--Estimated Cost to Complete. Make entries only when the contractor estimates that a particular expenditure category will vary from the amount negotiated. Realistic estimates are essential.

Column H--Estimated Costs at Completion. Complete only if an entry is made in Column G.

Column I--Negotiated Contract Amount. Enter in this column the costs agreed to during contract negotiations for all expenditure categories listed in Column A.

Column J--Variance (Over or Under). Complete only if an entry is made in Column H. When entrics have been made in Column H, this column should show the difference between the estimated costs at completion (Column H) and negotiated costs (Column I). When a line item varies by plus or minus 10 percent, i.e., the percentage arrived at by dividing Column J by Column I, an explanation of the variance should be submitted. In the case of an overrun (net negative variance), this submission shall not be dcemed as notice under the Limitation of Cost (Funds) Clause of the contract.

Modifications. List any modification in the amount negotiated for an item since the preceding report in the appropriate cost category.

Expenditures Not Negotiated. List any expenditure for an item for which no amount was negotiated (e.g., at the discretion of the contractor in performance of its contract) in the appropriate cost category and complete all columns except for I. Column J will of course show a 100 percent variance and will be explained along with those identified under J above.

ATTACHMENT 3

REPORT OF GOVERNMENT OWNED, CONTRACTOR HELD PROPERTY

CONTRACTOR:	CONTRACT NUMBER
ADDRESS	REPORT DATE:
	FISCAL YEAR:

CLASSIFICATION	BEGINNING OF PERIOD		ADJUSTMENTS			END OF PERIOD	
	# ITEMS	VALUE	# ITEMS ADDED	$ VALUE ADDED	# ITEMS DELETIONS	# ITEMS	VALUE
LAND >$25K							
LAND ≤$25K							
OTHER REAL >$25K							
OTHER REAL ≤$25K							
PROPERTY UNDER CONST >$25K							
PROPERTY UNDER CONST ≤$25K							
PLANT EQUIP >$25K							
PLANT EQUIP ≤$25K							
SPECIAL TOOLING >$25K							
SPECIAL TOOLING ≤$25K							
SPECIAL TEST EQUIP >$25K							
SPECIAL TEST EQUIP ≤$25K							
AGENCY PECULIAR >$25K							
AGENCY PECULIAR ≤$25K							
MATERIAL >$25K (CUMULATIVE)							
PROPERTY UNDER MFR >$25K							
PROPERTY UNDER MFR ≤$25K							

SIGNED BY:

(SIGNATURE) _____

(NAME PRINTED) _____

(TITLE) _____

DATE SIGNED:

_____

(TELEPHONE) _____

Updated—23 Feb 2011
Appendix W. Milestone Table for Base Period
Period of Performance:
24 February 2011 – 23 February 2014

WBS Number	Milestone Number	Milestone Title	Target for Completion	Change in Period of Performance
1.2	CLIN 0001	CLIN 0001: Product Development Plan	25 May 2011	
1.3	CLIN 0002	CLIN 0002: Clinical Development and Regulatory Plan	25 May 2011	
1.4	CLIN 0003	CLIN 0003: Manufacturing Facility Plan (Seasonal & Pandemic)	21 Nov 2011	
1.5	CLIN 0004	CLIN 0004: Feasibility Plan (Pandemic)	28 Feb 2012	
1.6	CLIN 0005A	CLIN 0005A: Contractor Defined Milestones - Seasonal	16 Dec 2013	
1.6.1	*0005A.1*	*Milestone 0005A.1 Process Development*	*13 Feb 2012*	
1.6.1.1	0005A.1.1	Milestone 0005A.1.1: Provide process robustness and product characterization (identify and quantify all impurities)	29 Jul 2011	
1.6.1.2	0005A.1.2	Milestone 0005A.1.2: Final draft specs for products to be employed during Ph 3 consistency lot manufacture	03 Oct 2011	
1.6.1.3	0005A.1.3	Milestone 0005A.1.3: Ensure that passage control and functional testing support commercial scale manufacturing	15 Jul 2011	
1.6.1.4	0005A.1.4	Milestone 0005A.1.4: Demonstrate process lock at 1000L bioreactor scale	12 Jul 2011	
1.6.1.5	0005A.1.5	Milestone 0005A.1.5: Provide full PD documentation to support EOP2 meeting	12 Sep 2011	
1.6.1.6	0005A.1.6	Milestone 0005A.1.6: Provide Process Validation master Plan and specific process validation protocols to support Ph3 consistency lot manufacturing	25 Oct 2011	
1.6.1.7	0005A.1.7	Milestone 0005A.1.7: Complete draft specs for virus banking	13 Feb 2012	
1.6.1.8	0005A.1.8	Milestone 0005A.1.8: Demonstrate adequate viral stock passage stability and productivity towards supporting full scale commercial production	30 Jun 2011	
1.6.2	*0005A.2*	*Milestone 0005A.2: Preclinical & Toxicology*	*06 Dec 2013*	

WBS Number	Milestone Number	Milestone Title	Target for Completion	Change in Period of Performance
1.6.2.3	0011A.2.1	Milestone 0011A.2.1: Reproductive Toxicology Study & Milestone 0011A.2.2: Repeat Dose Toxicology Study	06 Dec 2013	From Option to Base
1.6.3	***0005A.3***	***Milestone 0005A.3: Manufacturing***	***07 Jun 2011***	
1.6.3.1	Na	Phase 2a (Study 204) Manufacturing	19 Apr 2011	
1.6.3.2	0005A.3.1	Milestone 0005A.3.1 Ph 3 & Consistency Lots Manufacturing [Initiate manufacturing of Ph 3 clinical trial material]	12 Mar 2012	
1.6.3.3	0005A.3.2	Milestone 0005A.3.2 Facility Modifications for Phase 3	18 Oct 2011	
1.6.4	***0005A.4***	***Milestone 0005A.4: Testing and Release***	***19 Aug 2013***	
1.6.4.1	0005A.4.1	Milestone 0005A.4.1 Complete all master and working virus stock testing	24 Oct 2011	
1.6.4.2	0005A.4.2	Milestone 0005A.4.2 Complete all master and working cell bank testing, including EOP testing	19 Aug 2013	
1.6.5	***0005A.5***	***Milestone 0005A.5: Stability Program***	***16 Dec 2013***	
1.6.5.1	0005A.5.1	Milestone 0005A.5.1 Demonstrate adequate bulk and final container stability for seasonal vaccine	16 Dec 2013	
(formerly 2.2.5.2)	0011A.5.2	Milestone 0011A.5.2: Stability Program for Consistency Lots	27 Aug 2013	From Option to Base
1.6.6	***0005A.6***	***Milestone 0005A.6: Analytical***	***21 May 2012***	
1.6.6.1 (formerly 1.6.6.2)	0005A.6.1	Milestone 0005A.6.1 Validate QC Assays for Release of Seasonal Vaccine by end of Phase 2	21 May 2012	
1.6.7	***0005A.7***	***Milestone 0005A.7: Clinical Development***	***13 Mar 2013***	
1.6.7.1	0005A.7.1	Phase 2 Seasonal (Study #204) Study (Seasonal Trivalent): Phase 2a Healthy Adult Dose Ranging Study (18-49 y.o.))	27 Apr 2012	
1.6.7.2 (formerly 2.2.7.1)	0011A.7.1	Milestone 0011A.7.1: Phase 3 Immunogenicity & Consistency Lots Study	13 Mar 2013	From Option to Base
1.6.7.3 (formerly 2.2.7.6)	0011.A.7.1a	Milestone 0011.A.7.1a: Phase 2b Elderly Non-Inferiority	25 Jan 2013	
1.6.8	***0005A.8***	***Milestone 0005A.8: Regulatory***	***26 Jun 2012***	
1.6.8.1 – 1.6.8.6	0005A.8.1	IND Activities for Phase2a	01 Jul 2011	
1.6.8.7 (formerly 1.6.8.2)	0005A.8.2	End of Phase 2 (EOP2) Meeting	14 May 2012	
1.6.8.8 (formerly 2.2.8.1)	0011A.8.1	Milestone 0011A.8.1: IND	26 Jun 2012	From Option to Base

WBS Number	Milestone Number	Milestone Title	Target for Completion	Change in Period of Performance
1.7	**CLIN 0005B**	**CLIN 0005B: Contractor Defined Milestones – H5N1 Pandemic**	**23 Feb 2014**	
1.7.1	***0005B.1***	***Milestone 0005B.1: Process Development***	***03 Oct 2011***	
1.7.1.1	0005B.1.1	Milestone 0005.B.1.1 Finalize draft specifications for NOVASOME adjuvanted product by end of base period	03 Oct 2011	
1.7.1.2	0005B.1.2	Milestone 0005.B.1.2 Finalize formula and define manufacturing process for NOVASOME adjuvant	19 May 2011	
1.7.1.3	0005B.1.3	Milestone 0005.B.1.3 Complete draft specifications for virus banking by end of Base Period	12 Aug 2011	
1.7.2	***0005B.2***	***Milestone 0005B.2: Preclinical & Toxicology***	***27 Jan 2014***	
1.7.2.2	0005B.2.1	Milestone 0005B.2.1 Complete toxicology study with H5N1 VLPs with Novasomes Adjuvant	30 Nov 2011	
1.7.2.4	0005B.2.1	Milestone 0005B.2.1 Complete toxicology study with H5N1 VLPs & IDRI Adjuvant	01 Nov 2011	
1.7.2.6 (formerly 2.3.2.1)	0011B.2.1	Milestone 0011B.2.1: Reproductive Toxicology Study	27 Jan 2014	From Option to Base
1.7.2.7 (formerly 2.3.2.2)	0011B.2.2	Milestone 0011B.2.2: Repeat Dose Toxicology Study	27 Jan 2014	From Option to Base
1.7.3	***0005B.3***	***Milestone 0005B.3: Manufacturing***	***29 Jul 2013***	
1.7.3.1	0005B.3.1	Milestone 0005B.3.1 Manufacture and release preclinical lot of VLPs (H5N1 Pandemic)	10 Nov 2010	
1.7.3.2	0005B.3.2	Milestone 0005B.3.2 Manufacture GMP H5N1 VLPs	26 Apr 2011	
1.7.3.3	0005B.3.3	Milestone 0005B.3.3 Manufacture Preclinical Lot of Novasomes	06 Oct 2010	
1.7.3.4	0005B.3.4	Milestone 0005B.3.4 Release two (2) GMP lots of Novasomes by Month six (6)	28 Aug 2011	
1.7.3.5	N/A	Acquire supply of GMP IDRI Adjuvant for Preclinical Use	14 Jan 2011	
1.7.3.6	N/A	Acquire supply of GMP IDRI Adjuvant for Toxicology Study and Phase 1 Clinical Trial	24 Jun 2011	
1.7.3.8 (formerly 2.3.3.1)	0011B.3.1	Milestone 0011B.3.1: Phase 2a Healthy Adult & Elderly Adult Dose-Ranging Study & Phase 2a Pediatric Study Supply Manufacturing	20 Apr 2012	From Option to Base
1.7.3.8 (formerly 2.3.3.2)	0011B.3.2	Milestone 0011B.3.2: Phase 2b Adult Confirmatory and Phase 2b Pediatric Confirmatory Studies Supply Manufacturing (H5N1 VLPs)	06 Nov 2012	From Option to Base

WBS Number	Milestone Number	Milestone Title	Target for Completion	Change in Period of Performance
1.7.4	***0005B.4***	***Milestone 0005B.4: Testing and Release***	***01 Oct 2013***	
1.7.4.6 (formerly 2.3.4.3)	0011B.4.1	Milestone 0011B.4.1: Phase 2a Healthy Adult & Elderly Adult Dose-Ranging Study & Phase 2a Pediatric Study Supply Testing & Release (H5N1 VLPs)	25 Jun 2012	From Option to Base
1.7.4.7 (formerly 2.3.4.4)	0011B.4.2	Milestone 0011B.4.2: Phase 2b Adult Confirmatory and Phase 2b Pediatric Confirmatory Studies Supply Testing & Release (H5N1 VLPs)	10 Jan 2013	From Option to Base
1.7.5	***0005B.5***	***Milestone 0005B.5: Stability Program***	***08 Feb 2014***	
1.7.5.3	0005B.5.1	Milestone 0005B.5.1 Demonstrate adequate bulk and final container stability by end of Base Period	08 Feb 2014	
1.7.6	***0005B.6***	***Milestone 0005B.6: Clinical Development***	***03 Feb 2014***	
1.7.6.1	0005B.6.1	Milestone 0005B.6.1A Deliver Day 42 HI data from Phase 1 trial with adjuvanted H5N1 VLP Vaccine (NOVASOMES PATHWAY)	09 Apr 2012	
1.7.6.2	0005B.6.1	Milestone 0005B.6.1B Deliver Day 42 HI data from Phase 1 trial with adjuvanted H5N1 VLP Vaccine (IDRI ADJUVANT PATHWAY)	02 Apr 2012	
1.7.6.3 (formerly 2.3.6.2)	0011B.6.2	Milestone 0011.B.6.2: Phase 2a Healthy Adult & Elderly Adult Dose-Ranging Study and Phase 2b Adult Confirmatory Study	03 Feb 2014	From Option to Base
1.7.7	***0005B.7***	***Milestone 0005B.7: Regulatory***	***23 Feb 2014***	
1.7.7.3	0005B.7.1	IND for Adjuvanted Pandemic Vaccine (Milestone 005B.7.1 Submit IND for adjuvanted Pandemic Phase 1) (IDRI Adjuvant)	22 Nov 2011	
1.7.7.4	N/A	IND for Adjuvanted Pandemic Vaccine Phase 1 (Novasomes)	01 Dec 2011	
1.7.7.5 (formerly 2.3.7.9)	0011B.7.8	Milestone 0011B.7.8: File IND Amendment for Phase 2a Healthy Adult & Elderly Adult Dose-ranging Study	09 Aug 2012	From Option to Base
1.7.7.6 (formerly 2.3.7.2)	0011B.7.2	Milestone 0011B.7.2: File IND Amendment for Phase 2b Adult Confirmatory Study	15 Nov 2013	From Option to Base
1.7.7.7 (formerly 2.3.7.1)	0011B.7.1	Milestone 0011B.7.1: File IND Amendment for Phase 2a Pediatric Study	23 Jan 2014	From Option to Base
1.8	**CLIN 0006**	**CLIN 0006: Draft Security Plan**	**27 Mar 2011**	
1.9	**CLIN 0007**	**CLIN 0007: Final Security Plan**	**30 May 2012**	

WBS Number	Milestone Number	Milestone Title	Target for Completion	Change in Period of Performance
1.10	CLIN 0008	CLIN 0008: Technical Progress Reports (Including EVM) (35 each)	12 Feb 2014	
1.11	CLIN 0009	CLIN 0009: Draft Final Report	25 Dec 2013	
1.12	CLIN 0010	CLIN 0010: Final Report	08 Feb 2014	