EX-10.1 2 a101-bardaadm2012agree.htm EXHIBIT 10.1

Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) would likely cause competitive harm to the Company, if publicly disclosed. Double asterisks denote omissions.

Exhibit 10.1

AWARD/CONTRACT	1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)	RATING	PAGE OF PAGES 1 55
2. CONTRACT (*Proc. Inst. Indent.*) NO. HHSO100201200004I	3. EFFECTIVE DATE 06/15/2012	4. REQUISITION/PURCHASE REQUEST/PROJECT NO. N/A	

5. ISSUED BY CODE	HHS/OS/ASPR/BARDA	6. ADMINISTERED BY *(if other than Item 5)*	CODE
HHS/OS/ASPR/AMOG 330 Independence Ave., SW, Room G-640 Washington, DC 20201			

7. NAME AND ADDRESS OF CONTRACTOR *(No., street, county, State and ZIP Code)*	8. DELIVERY	
Emergent Manufacturing Operations Baltimore LLC 5901 E. Lombard St. Baltimore, MD 21224	FOB ORIGIN Other *(See below)*	
	9. DISCOUNT FOR PROMPT PAYMENT	
DUNS: [**] TIN: [**]	10. SUBMIT INVOICES (4 copies unless otherwise specified) TO THE ADDRESS SHOWN IN	ITEM See Section G
CODE / FACILITY CODE		

11. SHIP TO/MARK FOR CODE		12. PAYMENT WILL BE MADE BY	CODE	PSC
HHS/OS/ASPR/BARDA		See Section G		
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 See Section G5		

15A. ITEM NO.	15B. SUPPLIES/SERVICES	15C. QUANTITY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT
	See Schedule (for Pricing)				
15G. TOTAL AMOUNT OF CONTRACT					$ 99,941,719.80

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

17. CONTRACTOR'S NEGOTIATED AGREEMENT *(Contractor is required to sign this document and return __2__ copies to issuing office.)*	18. AWARD *(Contractor is required to sign this document.) Your bid on* Solicitation Number _____,
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.)*	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 soliciation and your bid, and (b) this award/contract. No further contractual document is necessary. (Block 18 should be checked only when awarding a sealed-bid contract.)
19A. NAME AND TITLE OF SIGNER *(Type or print)*	20A. NAME OF CONTRACTING OFFICER

illegible		[**] Contracting Officer	
19B. NAME OF CONTRACTOR	19C. DATE SIGNED	20B. UNITED STATES OF AMERICA	20C. DATE SIGNED
BY /s/ illegible *(Signature of person authorized to sign)*		BY /s/ [**] *(Signature of Contracting Officer)*	6/15/2012

AUTHORIZED FOR LOCAL REPRODUCTION
Previous edition is NOT usable

STANDARD FORM 26 (REV. 5/2011)
Prescribed by GSA – FAR (48 CFR) 53.214(a)

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

B.1. Brief Description of Supplies or Services

The Department of Health and Human Services (HHS), Biomedical Advanced Research and Development Authority (BARD A) and the Office of Acquisitions Management, Contracts & Grants (AMCG) seek to establish Centers for Innovation in Advanced Development and Manufacturing (the 'Centers') as public-private partnerships that share facility construction costs, facilitate medical countermeasure (MCM) product development, ensure domestic vaccine manufacturing surge capacity, and provide workforce development training programs. These U.S.-based Centers are expected to provide, on a routine basis, core services including advanced development and manufacturing capabilities for chemical, biological, radiological and nuclear (CBRN) MCMs to address national preparedness and response priorities and needs. HHS/BARDA requires the services of Contractor(s) to provide core advanced development ("industrialization") and manufacturing services to other commercial partners under contract to the U.S. Government (USG) for development of biopharmaceuticals against CBRN threats. Additionally, HHS/BARDA requires Contractor(s) to provide new or renovated manufacturing facilities utilizing flexible manufacturing and modem platform technologies to produce pandemic influenza vaccine and MCMs for outbreaks of an emerging infectious pathogen or currently known or unknown threats. Further, HHS/BARDA requires Contractor(s) to provide a workforce development training program to enhance and maintain the U.S.-based ability to produce these MCMs.

The work performed at these Centers will be coordinated and integrated by HHS/BARDA with programs from other USG agencies to provide long-term solutions that address the medical consequences of known and unknown threats. The period of performance for the contract includes a multi-year base period and one-year option periods which in total shall not exceed 25 years.

B.2. Contract Line Item Numbers (CLINS)

Facility(s) design, construction, commissioning and validation; and availability to provide pandemic influenza vaccine in an emergency, shall take place during the base period of performance.

During the option periods, Service Task/Delivery Orders for requirements such as CBRN advanced development, Pandemic Influenza Vaccine Surge production (including warm-based), Biopharmaceutical Bulk Manufacturing, Formulation, Filling/finishing, Storage, and Shipping may be issued upon agreement by the parties. Option periods may be exercised by the Government by issuance of a unilateral contract modification. Each Service Task Order will specify its own period of performance which may differ from the option period of performance; however, the Service Task/Delivery Order period of performance shall in no event exceed the contract period of performance if all option years are exercised. Task orders for core advanced development and manufacturing services may be issued during the base period of the contract and all option years.

Once [**] is commissioned and validated, it is the Contractor's responsibility to maintain a cGMP manufacturing facility throughout the entire period of performance of the contract. Once the [**] Pilot Plant is commissioned and validated for its intended purpose, it is the Contractor's responsibility to maintain the intended state throughout the entire period of performance of the contract.

B.2.1. Base Period Bid Schedule

B.2.1.1. Lump Sum - Base Period for Pandemic Influenza Vaccine Candidate (CLIN 0001)

This contract includes CLIN 0001 and a description of the Contractor's technical approach toward securing a Pandemic Influenza Vaccine Candidate currently under development. The description shall include the Contractor's approach to obtaining access to all Intellectual Property (IP) necessary for the process development in accordance with the IP requirements specified under Federal Acquisition Regulations ("FAR") Part 27-Patents Data and Copyrights. The term IP as used in this section, as well as Section B.3.6 below, shall include any and all Inventions as defined under FAR Section 27.301, and any and all Data as defined under FAR Section 27.401.

All IP license rights necessary for the facility(s) process development and manufacturing of a Pandemic Influenza Vaccine Candidate will be under CLIN 0001. The Contractor will be prohibited from incurring any costs under other pre-defined CLINs that further the process development and the design/build of facility(s) in support of the pandemic influenza vaccine manufacturing surge capacity prior to receipt of the Contracting Officer's written authorization.

No later than [**] after award the Contractor must provide the Contracting Officer with a written description of the specific Pandemic Influenza Vaccine Candidate that it intends to utilize in order to meet the requirements under Pandemic Influenza Vaccine Surge Capacity (the "Vaccine Candidate"), as well as written description of all IP necessary to further the process development of the Influenza Vaccine Candidate. If required by the Contractor, HHS will identify to the Contractor a suitable Pandemic Influenza Vaccine Candidate currently under development with the USG that can be utilized by the Contractor as the specific Influenza Vaccine Candidate to be used in meeting the CLIN 0001 requirement. The Contractor has the option of using that Influenza Vaccine Candidate or proposing another Influenza Vaccine Candidate. The Contractor's acceptance of an Influenza Vaccine Candidate that is identified by HHS will not relieve the Contractor from complying with any of the IP requirements specified in this section or extend the time frames for complying with those provisions. The Contractor shall provide HHS with a written description of all IP necessary to complete process development leading to manufacturing surge capacity of the Pandemic Influenza Vaccine Candidate in the identified facility(s) ("Description"). The Description must identify the basis for offering HHS less than unlimited rights to any pre-existing IP identified in the Description that will be utilized in the process development of the Pandemic Influenza Vaccine Candidate. The Description shall also include written verification that the Contractor has secured all license rights that are necessary to utilize any and all IP for the process development of the Influenza Vaccine Candidate in accordance with the IP rights granted to HHS, the Contractor, and any and all and subcontractors and/or teaming partners whose IP will be utilized during the development process, as specified under FAR Clause 52.227-11, FAR Clause 52.227-11 as amended in any applicable subcontract

and/or teaming agreement, FAR Clause 52.227-14, and FAR Clause 52.227-14 as amended in any applicable subcontract and/or teaming agreement. When requested by the Contracting Officer, the Contractor shall provide HHS with written copies of any and all applicable licenses that have been executed with any and all subcontractors and/or teaming partners who's IP will be utilized during the process development of the Pandemic Influenza Vaccine Candidate.

FAR Clause 52.227-1, FAR Clause 52.227-3, FAR Clause 52.227-11, FAR Clause 52.227-14 and FAR Clause 52.227-16 are incorporated by reference into this Contract.

CLIN	Item Description	Qty	Unit of Issue	Cost	Total Cost
0001	Pandemic Influenza Vaccine Candidate (FFP)	1	Lump Sum	[**]	[**]
TOTAL Cost (CLIN 0001):					[**]

CLIN 0001 Pricing Schedule

Payment 1: $[**] Upon [**].

Payment 2: $[**] Upon [**].

Payment 3: $[**] Upon [**].

Payment 4: $[**] Upon [**].

Payment 5: $[**] Upon [**].

Payment 6: $[**] Upon [**].

B.2.1.2. Cost-Share - Base Period for Facility Design, Construction, Validation Activities & Pandemic Influenza Vaccine Surge Capacity

The base period shall be cost-sharing (except for 0001). The base period provides for new facilities (design, construction, commissioning and validation) capable of providing core advanced development and flexible manufacturing services for CBRN medical countermeasures and, in an emergency, production of pandemic influenza vaccine.

Funding shall be provided for the total cost of performance as defined under CLIN 0002 from HHS and Emergent Manufacturing Operations Baltimore LLC. The percentages of cost-share are determined in the Pricing Schedule below. The Contractor shall maintain records of all contract costs (including costs claimed by the Contractor as being its share) and such records shall be subject to the Audit and Records-Negotiation clause of this contract.

The Contractor shall have ownership/title or unencumbered access to designated property/land for the construction of new facility(s) and/or ownership/title or unencumbered access to designated structures for retrofitting.

The cost share percentages listed in the Pricing Schedule below shall not be exceeded.

BASE PERIOD - June 15, 2012 through June 14, 2020

CLIN	Item Description:		Not To Exceed Contractor Cost Share	Not To Exceed USG Cost Share	Not To Exceed Total Cost
0002	Facility Design, Construction, Validation Activities & Pandemic Influenza Vaccine Surge Capacity	Cost-share	[**]	[**]	[**]

CLIN 0001 Pricing Schedule

Payment 1: $[**] Upon [**].

Payment 2: $[**] Upon [**].

Payment 3: $[**] Upon [**].

Payment 4: $[**] Upon [**].

Payment 5: $[**] Upon [**].

Payment 6: $[**] Upon [**].

B.2.1.2. Cost-Share - Base Period for Facility Design, Construction, Validation Activities & Pandemic Influenza Vaccine Surge Capacity

The base period shall be cost-sharing (except for 0001). The base period provides for new facilities (design, construction, commissioning and validation) capable of providing core advanced development and flexible manufacturing services for CBRN medical countermeasures and, in an emergency, production of pandemic influenza vaccine.

Funding shall be provided for the total cost of performance as defined under CLIN 0002 from HHS and Emergent Manufacturing Operations Baltimore LLC. The percentages of cost-share are determined in the Pricing Schedule below. The Contractor shall maintain records of all contract costs (including costs claimed by the Contractor as being its share) and such records shall be subject to the Audit and Records-Negotiation clause of this contract.

The Contractor shall have ownership/title or unencumbered access to designated property/land for the construction of new facility(s) and/or ownership/title or unencumbered access to designated structures for retrofitting.

The cost share percentages listed in the Pricing Schedule below shall not be exceeded.

BASE PERIOD - June 15, 2012 through June 14, 2020

CLIN	Item Description		Not To Exceed Contractor Cost Share	Not To Exceed USG Cost Share	Not To Exceed Total Cost‘
0002	Facility Design, Construction, Validation Activities & Pandemic Influenza Vaccine Surge Capacity	Cost-share	[**]	[**]	[**]

Pricing Schedule (CLIN 0002)

Sub-CLIN	Item Description	Percent Gov/Ktr	Contractor Cost Share	USG Cost Share	Total Cost
0002.1	**[**] Pilot Plant —Facility Design, Construction and Commissioning**	[**]	**[**]**	**[**]**	**[**]**
0002.2	**[**] - Construction, Commissioning/Validation and Qualification**	[**]	**[**]**	**[**]**	**[**]**
0002.3	**Licensure of Pandemic Influenza Vaccine in Baltimore facility**	[**]	**[**]**	**[**]**	**[**]**
0002.4	**Project Management**	[**]	**[**]**	**[**]**	**[**]**
0002.5	**Security**	[**]	**[**]**	**[**]**	**[**]**
0002.6	**Workforce Development Program (Plan Development)**	[**]	**[**]**	**[**]**	**[**]**

B.2.2. Option Period(s) Bid Schedule

B.2.2.1. Option Period for ADM Core Services, Warm Base Influenza Vaccine Production, Pandemic Influenza Vaccine Production and Facility Readiness Reimbursement

The USG will provide one hundred percent (100%) of the allowable costs for core services for medical countermeasure Advanced Development and Manufacturing (ADM). HHS will not fund activities or supplies of the Contractor outside of the scope of this contract in these facilities under this contract. Activities or supplies of the Contractor in these facilities for other HHS contracts shall be funded under the applicable contract. Task orders shall be executed utilizing U.S.-based facilities.

Following contract award, actual Service Task/Delivery Orders may be issued to the Contractor as needed by HHS. Actual task order requirements will reflect the actual labor rates of the proposed staff in effect when the task order is issued. The terms and conditions set forth in this contract will always apply.

The USG will provide one hundred percent (100%) of the total funding for warm base influenza vaccine readiness activities and pandemic influenza vaccine production during an emergency. The USG will provide for up to [**] percent ([**]%) of the total annual maintenance and operating costs of [**] for Core Services Readiness.

Service Task/Delivery Orders maybe issued for requirements such as CBRN advanced development, Pandemic Influenza Vaccine Surge production(including warm-based), Biopharmaceutical Bulk Manufacturing, Formulation, Filling/finishing, Storage and Shipping.

Costs contributed by the Contractor shall not be charged to the Government under any other contract, grant, or cooperative agreement (including allocation to other grants, contracts, or cooperative agreements as part of an independent research and development program).

Option Period I - June 15, 2013 through June 14, 2014

CLIN	Description	Fee Percentage (CPFF)	Not to Exceed Ceiling Price
0003	Core Services Readiness	[**]	N/A
0004	Pandemic Influenza Vaccine Surge Readiness	[**]	N/A
0005	Workforce Development	[**]	[**]
0006	Service Task/Delivery Orders	Type of Contract TBN	[**]

Option Period II - June 15, 2014 through June 14, 2015

CLIN	Description	Fee Percentage (CPFF)	Not to Exceed Ceiling Price
0007	Core Services Readiness	[**]	N/A
0008	Pandemic Influenza Vaccine Surge Readiness	[**]	N/A
0009	Workforce Development	[**]	[**]
0010	Service Task/Delivery Orders	Type of Contract TBN	[**]

Option Period III - June 15, 2015 through June 14, 2016

CLIN	Description	Fee Percentage (CPFF)	Not to Exceed Ceiling Price
0011	Core Services Readiness	[**]	[**]
0012	Pandemic Influenza Vaccine Surge Readiness	[**]	N/A
0013	Workforce Development	[**]	[**]
0014	Service Task/Delivery Orders	Type of Contract TBN	[**]

Option Period IV - Jane 15, 2016 through June 14, 2017

CLIN	Description	Fee Percentage (CPFF)	Not to Exceed Ceiling Price
0015	Core Services Readiness	[**]	[**]
0016	Pandemic Influenza Vaccine Surge Readiness	[**]	N/A
0017	Workforce Development	[**]	[**]
0018	Service Task/Delivery Orders	Type of Contract TBN	[**]

Option Period V - June 15, 2017 through June 14, 2018

CLIN	Description	Fee Percentage (CPFF)	Not to Exceed Ceiling Price
0019	Core Services Readiness	[**]	[**]
0020	Pandemic Influenza Vaccine Surge Readiness	[**]	N/A
0021	Workforce Development	[**]	[**]
0022	Service Task/Delivery Orders	Type of Contract TBN	[**]

Option Period VI - June 15, 2018 through June 14, 2019

CLIN	Description	Fee Percentage (CPFF)	Not to Exceed Ceiling Price
0023	Core Services Readiness	[**]	[**]
0024	Pandemic Influenza Vaccine Surge Readiness	[**]	N/A
0025	Workforce Development	[**]	[**]
0026	Service Task/Delivery Orders	Type of Contract TBN	[**]

Option Period VII - June 15, 2019 through June 14, 2020

CLIN	Description	Fee Percentage (CPFF)	Not to Exceed Ceiling Price
0027	Core Services Readiness	[**]	[**]
0028	Pandemic Influenza Vaccine Surge Readiness	[**]	N/A
0029	Workforce Development	[**]	[**]
0030	Service Task/Delivery Orders	Type of Contract TBN	[**]

Option Period VIII - June 15, 2020 through June 14, 2021

CLIN	Description	Fee Percentage (CPFF)	Not to Exceed Ceiling Price
0031	Core Services Readiness .	[**]	[**]
0032	Pandemic Influenza Vaccine Surge Readiness	[**]	[**]
0033	Workforce Development	[**]	[**]
0034	Service Task/Delivery Orders	Type of Contract TBN	[**]

Option Period IX - June 15, 2021 through June 14, 2022

CLIN	Description	Fee Percentage (CPFF)	Not to Exceed Ceiling Price
0035	Core Services Readiness	[**]	[**]
0036	Pandemic Influenza Vaccine Surge Readiness	[**]	[**]
0037	Workforce Development	[**]	[**]
0038	Service Task/Delivery Orders	Type of Contract TBN	[**]

Option Period X - June 15, 2022 through June 14, 2023

CLIN	Description	Fee Percentage (CPFF)	Not to Exceed Ceiling Price
0039	Core Services Readiness	[**]	[**]
0040	Pandemic Influenza Vaccine Surge Readiness	[**]	[**]
0041	Workforce Development	[**]	[**]
0042	Service Task/Delivery Orders	Type of Contract TBN	[**]

Option Period XI - June 15, 2023 through June 14, 2024

CLIN	Description	Fee Percentage (CPFF)	Not to Exceed Ceiling Price
0043	Core Services Readiness	[**]	[**]
0044	Pandemic Influenza Vaccine Surge Readiness	[**]	[**]
0045	Workforce Development	[**]	[**]
0046	Service Task/Delivery Orders	Type of Contract TBN	[**]

Option Period XII - June 15, 2024 through Jane 14, 2025

CLIN	Description	Fee Percentage (CPFF)	Not to Exceed Ceiling Price
0047	Core Services Readiness	[**]	[**]
0048	Pandemic Influenza Vaccine Surge Readiness	[**]	[**]
0049 ‘	Workforce Development	[**]	[**]
0050	Service Task/Delivery Orders	Type of Contract TBN	[**]

Option Period XIII - June 15, 2025 through June 14, 2026

CLIN	Description	Fee Percentage (CPFF)	Not to Exceed Ceiling Price
0051	Core Services Readiness	[**]	[**]
0052	Pandemic Influenza Vaccine Surge Readiness	[**]	[**]
0053	Workforce Development	[**]	[**]
0054	Service Task/Delivery Orders	Type of Contract’ TBN	[**]

Option Period XIII - June 15, 2026 through June 14, 2027

CLIN	Description	Fee Percentage (CPFF)	Not to Exceed Ceiling Price
0055	Core Services Readiness	[**]	[**]
0056	Pandemic Influenza Vaccine Surge Readiness	[**]	[**]
0057	Workforce Development	[**]	[**]
0058	Service Task/Delivery Orders	Type of Contract TBN	[**]

Option Period XV - June 15, 2027 through June 14, 2028

CLIN	Description	Fee Percentage (CPFF)	Not to Exceed Ceiling Price
0059	Core Services Readiness	[**]	[**]
0060	Pandemic Influenza Vaccine Surge Readiness	[**]	[**]
0061	Workforce Development	[**]	[**]
0062	Service Task/Delivery Orders	Type of Contract TBN	[**]

Option Period XVI - June 15, 2028 through June 14, 2029

CLIN	Description	Fee Percentage (CPFF)	Not to Exceed Ceiling Price
0063	Core Services Readiness	[**]	[**]
0064	Pandemic Influenza Vaccine Surge Readiness	[**]	[**]
0065	Workforce Development	[**]	[**]
0066	Service Task/Delivery Orders	Type of Contract TBN	[**]

Option Period XVII - June 15, 2029 through June 14, 2030

CLIN	Description	Fee Percentage (CPFF)	Not to Exceed Ceiling Price
0067	Core Services Readiness	[**]	[**]
0068	Pandemic Influenza Vaccine Surge Readiness	[**]	[**]
0069	Workforce Development	[**]	[**]
0070	Service Task/Delivery Orders	Type of Contract TBN	[**]

Option Period XVIII - June 15, 2030 through June 14, 2031

CLIN	Description	Fee Percentage (CPFF)	Not to Exceed Ceiling Price
0071	Core Services Readiness	[**]	[**]
0072	Pandemic Influenza Vaccine Surge Readiness	[**]	[**]
0073	Workforce Development	[**]	[**]
0074	Service Task/Delivery Orders	Type of Contract TBN	[**]

Option Period XIX - June 15, 2031 through June 14, 2032

CLIN	Description	Fee Percentage (CPFF)	Not to Exceed Ceiling Price
0075	Core Services Readiness	[**]	[**]
0076	Pandemic Influenza Vaccine Surge Readiness	[**]	[**]
0077	Workforce Development	[**]	[**]
0078	Service Task/Delivery Orders	Type of Contract TBN	[**]

Option Period XX - June 15, 2032 through June 14, 2033

CLIN	Description	Fee Percentage (CPFF)	Not to Exceed Ceiling Price
0079	Core Services Readiness	[**]	[**]
0080	Pandemic Influenza Vaccine Surge Readiness	[**]	[**]
0081	Workforce Development	[**]	[**]
0082	Service Task/Delivery Orders	Type of Contract TBN	[**]

Option Period XXI - June 15, 2033 through June 14, 2034

CLIN	Description	Fee Percentage (CPFF)	Not to Exceed Ceiling Price
0083	Core Services Readiness	[**]	[**]
0084	Pandemic Influenza Vaccine Surge Readiness	[**]	[**]
0085	Workforce Development	[**]	[**]
0086	Service Task/Delivery Orders	Type of Contract TBN	[**]

Option Period XXII - June 15, 2034 through June 14, 2035

CLIN	Description	Fee Percentage (CPFF)	Not to Exceed Ceiling Price
0087	Core Services Readiness	[**]	[**]
0088	Pandemic Influenza Vaccine Surge Readiness	[**]	[**]
0089	Workforce Development	[**]	[**]
0090	Service Task/Delivery Orders	Type of Contract TBN	[**]

Option Period XXIII - June 15, 2035 through June 14, 2036

CLIN	Description	Fee Percentage (CPFF)	Not to Exceed Ceiling Price
0091	Core Services Readiness	[**]	[**]
0092	Pandemic Influenza Vaccine Surge Readiness	[**]	[**]
0093	Workforce Development	[**]	[**]
0094	Service Task/Delivery Orders	Type of Contract TBN	[**]

Option Period XXIV - June 15, 2036 through June 14, 2037

CLIN	Description	Fee Percentage (CPFF)	Not to Exceed Ceiling Price
0095	Core Services Readiness	[**]	[**]
0096	Pandemic Influenza Vaccine Surge Readiness	[**]	[**]
0097	Workforce Development	[**]	[**]
0098	Service Task/Delivery Orders	Type of Contract TBN	[**]

B.2.3. Minimum and Maximum Ordering Limitations and Ceiling Limitations

B.2.3.1. There is no minimum guarantee under the base period. If an option period is exercised, then the Government may provide a reimbursement for readiness (e.g. Core Services Readiness CLIN) for no more than [**] of facility(s) capacity for that option period as per the Statement of Work, if:

(1) The Government fails to issue a task order (or task orders) that reasonably keep the facility(s) in use for a negotiated period that calculates to [**] of overall capacity; or,

(2) The facility(s) usage time per an issued task order (or task orders) is less than [**] of the overall capacity. In this case the Contractor shall be entitled to Core Services Readiness costs that are equivalent to the difference between the percentage of time that the facility(s) was in use per the issued task order(s) and the [**] threshold.

B.2.3.1.1. The minimum ordering limitation shall be $[**] for core services.

B.2.3.1.2. The maximum ordering limitation for a single item or combination of items shall be $[**] for ADM core services.

B.2.3.1.3. As referenced in FAR 52.216-19 , the Contractor is not obligated to honor-

(1) Any order for a single item in excess of $[**]
(2) Any order for a combination of items in excess of $[**] or
(3) A series of orders from the same ordering office within [**] that together calls for quantities exceeding the limitation in (1) or (2) of this section.

B.2.3.1.4. The above Ordering Limitations are not applicable to Pandemic Influenza Vaccine Surge requirement for delivery of [**] doses within [**].

B.2.3.2. The ceiling limitation for Cost Plus Fixed Fee (CPFF) portion of the contract is defined in the Option Period Bid Schedule.

B.2.4. Fair Opportunity Ordering (for Core Services, Warm Base Vaccine Production, and Pandemic Influenza Vaccine Production)

In accordance with FAR §16.505, Ordering, the following procedures will be used to issue orders under the contract:

All work under this contract will be ordered through tire issuance of written “Task Order(s)” and “Delivery Order(s)” on an Optional Form 347 executed by the Contracting Officer. The Contracting Officer is the only individual authorized to issue orders under this contract. The Contractor shall only commence work upon receipt of a properly awarded written order executed by the Contracting Officer.

For orders exceeding the micro-purchase threshold, see FAR § 2.101, at the time of the order placement, and subject to the exceptions to the fair opportunity process, see FAR § 16.505(b)(2), the Government will place an order with the Contractor that provides the greatest overall benefit to the Government upon consideration of factors pertinent to an individual order.

Orders over $[**]-FAR 16.505(b)(l)(iii) - For task or delivery orders in excess of $[**], the requirement to provide all awardees a fair opportunity to be considered for each order shall include, at a minimum— (A) A notice of the task or delivery order that includes a clear statement of the agency’s requirements; (B) A reasonable response period; (C) Disclosure of the significant factors and sub-factors, including cost or price, that the agency expects to consider in evaluating proposals, and their relative importance; (D) Where award is made on a best value basis, a written statement documenting the basis for award and the relative importance of quality and price or cost factors; and (E) An opportunity for a post-award debriefing in accordance with paragraph (b)(4) of this section.

Fair opportunity to be considered for each order will be accomplished by the Contracting Officer issuing a Task/DeliveryOrder Request (T/DOR) to establish an adequate basis for fair opportunity consideration of placement of that order. The Contracting Officer may issue a T/DOR to fewer than all contract-holders. However, this will only occur if the other contract-holders have not obtained the proper validation for their facility. A T/DOR will be issued either in a written format that either has been executed by the Contracting Officer or sent via electronic mail directly from the Contracting Officer. A review pursuant to this subparagraph will be deemed adequate for fair opportunity consideration.

A T/DOR may provide a Statement of Objective or Statement of Work, order-specific factors to be used in the selection decision, reporting requirements, deliverables and delivery schedule, and any special instructions or terms applicable to the order. Selection factors for award will be specific for each individual order.

A T/DOR will request a written proposal to be prepared and submitted by the contract-holder to the Contracting Officer. The Contracting Officer will use the T/DOR proposal as one basis, or the sole basis, for the order placement decision. The T/DOR will set forth the specific requirements or objectives for the proposal, information that may be requested includes, but is not limited to, an approach to perform the work, technical and managerial resources, and schedule for performance identifying major milestones, conflict-of-interest certification, and price/cost itemized by price/cost elements. Unless otherwise specified in a T/DOR, a contract holder shall prepare and deliver a proposal within the timeframe stipulated in the T/DOR in order to receive consideration.

Orders placed hereunder will be executed on an OF 347 and will, at a minimum, contain the following information:

Date of order
Contract number and order number
Description of services, contract item number(s) and description, quantity, and price
Delivery or performance schedule
Place of delivery or performance (including consignee)
Any packaging, packing, and shipping instructions
Accounting and appropriation data
Delegation of a Task/Delivery Order COR, if applicable

Ombudsman: The name, address, telephone number, facsimile number and e-mail address of the agency task and delivery order ombudsman is available upon request to the Contracting Officer.

B.3. ADVANCED UNDERSTANDINGS

B.3.1. Priority Rating

HHS may assign a priority rating to any contract awarded under this solicitation. The Contracting Officer may unilaterally modify the task order(s) to add FAR Clause 52.211-15, Defense Priority and Allocation Requirements (Sep 1990) and assign a Health and Human Services priority rating under Defense Priorities and Systems Regulation (15 CFR 700).

B.3.2. Facility Ownership

The Contractor and the USG will share ownership of the portions of the facility to be retrofitted or newly constructed under this Contract, commensurate with the cost share arrangement. The USG ownership of facilities/materials/equipment procured under the terms of this contract and specified as required to prepare a facility(s) for occupancy shall be turned over to the Contractor upon receipt of the Occupancy Permit(s). Local laws and ordinances will govern when a newly constructed and/or retrofitted facility is suitable to occupy. USG ownership of process equipment/materials procured under the terms of this contract shall be turned over to the Contractor upon successful installation and commissioning/qualification of the equipment at the US-based facility specified in the Technical Proposal. During the execution of Option Periods, equipment/materials procured under an executed Task/Delivery Order would be considered Contractor Acquired USG property throughout the Period of Performance. Upon successful completion of a given Task Order, the Contracting Officer will direct the Contractor of the disposition of Contractor Acquired USG property, if applicable.

B.3.3. Failure to Meet Requirements - CLIN 0001

Failure to meet the licensing requirements within the [**] deadline specified under Section B. 2.1.1 shall constitute grounds for termination of any Contract awarded in response to this Solicitation. The termination shall be at the sole discretion of the Contacting Officer. In the

event that the Contractor fails to meet the [**] deadline specified under Section B. 2.1.1, and, as a result, the Contractor incurs additional performance costs necessary to meet any objective in the Contract, the Contractor will be responsible for those additional costs, and those incurred costs may not be charged to any CLIN in any Contract awarded in response to this Solicitation.

B.3.4. Costs

The Contractor shall insure the Contracting Officer receives all necessary cost elements, which will require the prior written approval of the Contracting Officer before the incurrence of cost (e.g., foreign travel, consultant fees, subcontracts). The Contracting Officer will determine all necessary cost elements and thresholds at the kick-off meeting and during the administration of the contract.

B.3.5. FDA Interactions

Offerors are encouraged to interact with the FDA prior to and during the process to review their proposed methodology related to facility construction and validation plans against current FDA guidelines in the development of CBRN medical countermeasures and influenza vaccines.

B.3.6. Intellectual Property for Development of Other CBRN Medical Countermeasures

Execution of an MCM Task Order will require a relationship between HHS, the firm that possesses rights to specific Intellectual Property (IP) required for the development effort (the “MCM IP Holder”), and the firm providing the Core Services under the Task/Delivery Order (the “Core Services Contractor”). The relationship must reflect the Parties’ rights to all IP developed and/or IP used in performance of the Task/Delivery Order, and be consistent with HHS’s IP rights per the Federal Acquisition Regulations (FAR) clauses described herein. Prior to execution of any MCM Task Order, the MCM IP Holder and/ or the Core Services Contractor shall provide Contracting Officer with a written description of all IP necessary to develop the MCM (the “Description”). The Description must identify the basis for offering HHS less than unlimited rights to any preexisting IP identified in the Description that will be utilized in performance of the MCM Task/Delivery Order. The Description shall also include written verification that the IP Holder will provide HHS with rights to any and all IP utilized or developed during performance of the MCM Task/Delivery Order as specified under FAR Clause 52.227-11, FAR Clause 52.227-11 as amended in any applicable subcontract and/or teaming agreement related to performance of the MCM Task/Delivery Order, FAR Clause 52.227-14 and FAR Clause 52.227-14 as amended in any applicable subcontract and/or teaming agreement (the “FAR Clauses”). The MCM IP Holder and the Core Services Contractor will remain free to negotiate any agreement for their own regarding their use of any of the IP utilized or developed during performance of an MCM Task/Delivery Order, so long as the negotiated agreement complies with the requirements under the FAR Clauses, and the terms contained in the agreement do not otherwise adversely affect the performance of work under the MCM Task/Delivery Order. When requested by the Contracting Officer, the agreement shall be furnished to the Contracting Officer within [**] after the agreement is finalized. All MCM Task/Delivery Orders will specifically incorporate the FAR Clauses and also FAR Clause 52.227-1 Authorization and Consent (DEC 2007) and FAR Clause 52.227-3 Patent Indemnity (APR 1984).

B.3.7. Good Faith Commitment

The Contractor acknowledges that performance under this contract is subject to negotiated partnering arrangements (e.g. intellectual property rights) and industry development/regulatory risks. The Contractor agrees to work in good faith with all partners, subcontractors, and other relevant parties to address issues relating to the development and regulatory process for any biopharmaceutical or biopharmaceutical manufacturing facility as they arise to reach agreement on a path forward, which shall include allowing the Contractor a reasonable period of time to address particular issues. Such issues include, but are not limited to, successful partnering arrangements, the determination of appropriate dosing levels, ongoing process developments and improvements, insuring adequate production capacity, and other aspects of the FDA regulatory approval process. Further, the FDA's failure to grant licensure, in and of itself, shall not be considered a default of the Contractor's obligations hereunder, so long as the Contractor performs in accordance with the Statement of Work and the Contractor's Technical Proposal incorporated by reference into the contract.

After completing the base period, or before if contractually capable, the Contractor shall propose on all T/DORs that are issued by the Government. Proposals exceeding $[**] shall include non-certified cost or pricing data unless a determination is made by the Contracting Officer that the exceptions in FAR 15.403-1 do not apply; in that case certified cost or pricing data is required as outlined in FAR 15.403-4 and 15.406-2. Failure to submit a proposal in accordance with the technologies and capabilities highlighted in a Contractor's statement of work, and/or a failure to provide a reasonable cost proposal based upon the cost or pricing data submitted, may result in a termination of the contract as prescribed in FAR 49.403. If this type of termination is determined by the Contracting Officer, the Government may seek other damages as prescribed in FAR 49.402-7, these damages may include but are not limited to construction costs and facility readiness reimbursement costs.

B.3.8. DETERMINATION OF READINESS

B.3.8.1. Readiness for Core Services

The Contractor shall be considered eligible for a core services readiness reimbursement when they have successfully demonstrated to the Contracting Officer that all of the core services included in the technical proposal are operational, qualified to the extent required, and available for use by the USG. Operational readiness will be verified by an onsite audit by the Contracting Officer and/or Contracting Officer's Representative (COR). The Contracting Officer will make a written determination as to readiness. The contactor must maintain the accepted conditions of operational readiness to be eligible for continued core services readiness reimbursement.

B.3.8.2. Pandemic Influenza Vaccine Surge Readiness

The contractor shall be considered eligible for a Pandemic Influenza Vaccine Surge readiness reimbursement when they have successfully demonstrated to the Contracting Officer that the facilities, utilities, equipment, quality systems and all associated operations that support Pandemic Influenza Vaccine surge capability are operational, qualified to the extent required and

available for use by the USG. Moreover, the data package from the Clinical Phase III and/or bridging study for the Pandemic Influenza Vaccine candidate must have been submitted to the FDA. Operational readiness will be verified by an onsite audit by the Contracting Officer and/or Contracting Officer's Representative (COR). The Contracting Officer will make a written determination as to Pandemic Influenza Vaccine Surge readiness. The contactor must maintain the accepted conditions of operational readiness to be eligible for continued Pandemic Influenza Vaccine Surge readiness reimbursement.

B.3.9. WORKFORCE DEVELOPMENT

The Contractor shall be considered eligible for workforce development task orders when they have successfully demonstrated to the Contracting Officer that they have established their workforce development program as stated in the Statement of Work (SOW). The workforce development program shall be verified and approved in writing by the Contracting Officer.

SECTION C - DESCRIPTIONS/SPECIFICATIONS/WORK OBJECTIVES

C.1. BACKGROUND

In the last ten years, the U.S. has experienced the destructive effects of both acts of terrorism and infectious disease outbreaks. While limited in scope, the anthrax attacks that followed were highly disruptive and suggested the impact that large-scale acts of bioterrorism would have if carried out successfully. Similarly, concerns have escalated that terrorist groups might obtain and use chemical, radiological, and nuclear weapons against civilian populations. Events of the last decade – the SARS epidemic of 2003, the global spread of H5N1 avian influenza, and the 2009-H1N1 pandemic – have also highlighted the persistent threats of pandemic influenza and emerging infectious diseases.

The U.S. Government (USG) has mobilized in many ways to meet such threats. Among the most prominent of these have been the efforts to develop safe and effective medical countermeasures (MCMs) against chemical, biological, radiological, and nuclear (CBRN) threats, pandemic influenza, and emerging infectious diseases. The need for MCMs to diagnose, prevent, mitigate, or treat the illness caused by such agents is clear, but their development has been hindered by the lack of viable markets for such products. The USG has addressed these market barriers by providing substantial support for the research, development, and procurement of MCMs. Many of the firms that have been attracted to bio-defense lack experience in the late stages of product development and have encountered significant challenges with the advanced development and manufacturing of their products.

Moreover, the U.S. biopharmaceutical industry as a whole has been in a state of flux, with many manufacturers and biotechnology firms shifting their production capabilities overseas. The decline of domestic manufacturing capacity jeopardizes a critical national infrastructure and raises concerns about where the workforce of the future will acquire the requisite skills and experience to support biopharmaceutical manufacturing and process development. The 2009 H1N1 influenza pandemic, in which the U.S. was dependent upon offshore manufacturers for a

significant portion of its vaccine supply, illustrated the vulnerability that such dependency entails.

These events and trends prompted the President and the Secretary of Health and Human Services to call for a critical review of the civilian Public Health Emergency Medical Countermeasures Enterprise (PHEMCE). This review, led by the U.S. Department of Health and Human Services (HHS) Assistant Secretary for Preparedness and Response (ASPR), resulted in the August 2010 publication of a report, *The Public Health Emergency Medical Countermeasures Review: Transforming the Enterprise to Meet Long-Range National Needs,* that articulated as a strategic imperative that "***Our nation must have the nimble, flexible capacity to produce MCMs rapidly in the face of any attack or threat, known or unknown, including a novel, previously unrecognized, naturally occurring emerging infectious disease.***"

To meet this imperative, the PHEMCE Review laid out a forward-looking strategy with the following critical elements:

- MCM investments that address current, future, and unknown threats
- A focus on nimble, multi-use technology platforms and products, when appropriate, to increase the likelihood of developing and procuring products in a cost-efficient and timely way and transform our response capacity
- Greater investment in regulatory innovation and regulatory science
- New, more collaborative approaches to public-private partnerships
- An emphasis on providing core advanced development and manufacturing services

To address these requirements, and to enhance domestic manufacturing capacity to rapidly produce and package an influenza vaccine for the American public in the face of a pandemic, the PHEMCE Review called for HHS and the Department of Defense (DoD) to establish Centers for Innovation in Advanced Development and Manufacturing (the "Centers") that could provide advanced development and manufacturing capabilities as core services for CBRN MCMs to address national security and to augment public health needs on a cost-effective, reliable and sustainable basis.

As presently envisioned, the Centers will connect our industrial partners with needed technical and regulatory expertise during the most challenging stages of product development and industrialization. HHS/BARDA will coordinate the activities of the Centers and will provide guidance and oversight in terms of specific product objectives and contract management in collaboration with National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), and Department of Defense (DoD). Additional core services (e.g., clinical trials, animal challenge studies) that are provided already by the USG for product development will be coordinated and integrated with services offered by the Centers. These Centers will work to improve the application of flexible manufacturing and any other emerging technologies to support MCM product development.

Establishing the Centers with different capabilities and manufacturing platforms will allow for maximum flexibility and adaptability to respond to changes in technology and/or disease threats. As an element of critical national infrastructure, the Centers will augment existing U.S.-based

manufacturing capacity to produce vaccines and other biologics against emerging infectious diseases and currently known or unknown threats, including pandemic influenza, during public health emergencies. The Centers will provide an ideal setting for needed workforce training and development. As a nexus of public, private and academic partnership, the Centers will reinvigorate the workforce and promote the development of the next generation of biopharmaceutical scientists and engineers.

Previous HHS investments into cost-sharing public-private partnerships have included the establishment of a domestic cell-based influenza vaccine manufacturing facility in 2009 and the retrofitting of domestic facilities to produce egg-based influenza vaccine in 2007 that were utilized for production of 2009 H1N1 pandemic influenza vaccine. A major objective of HHS/BARDA is to further expand U.S.-based biopharmaceutical manufacturing surge capacity through the awarding of multiple cost sharing contracts to private sector partners in order to retrofit or construct new facilities for commercial-scale manufacturing using innovative platform technologies. These initiatives will be coordinated with concomitant DoD efforts to ensure availability of needed MCMs for the U.S. war-fighter.

The envisioned result is an integrated, domestic infrastructure based on strategic partnerships with industry and/or academia with multi-purpose capabilities to develop and manufacture new biopharmaceutical MCMs in a timely manner to protect the U.S. civilian population. The Centers for Innovation in Advanced Development and Manufacturing would develop the next generation of the MCM production workforce through training opportunities, including graduate level training programs, for current and future industry and government scientists engaged in advanced development and manufacturing of MCMs. The Centers would also be used to explore emerging technologies that could be applied to current or future MCM development efforts to reduce risk, increase yield and ultimately to reduce total life-cycle costs. This could be achieved through flexible manufacturing, consolidating other costly product development expenditures, or any other economy-of-scale opportunities.

C.2. STATEMENT OF WORK (SOW)

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

C.2.1. Overview/Scope

Emergent’s Center for Innovation in Advanced Development and Manufacture (CIADM) shall expand domestic biopharmaceutical (vaccines and other CBRN biologic MCMs) production capacity for advanced development at pilot and commercial scale to augment existing manufacturing infrastructure. The CIADM shall provide a capability to incorporate emerging and innovative technologies that could be applied to current or future USG MCM development efforts to reduce risk, increase yield, and/or reduce total life cycle costs.

The SOW for this contract includes addition of a [**] facility, provision of advanced development and manufacturing core services, provision of surge capacity for pandemic influenza vaccine manufacturing, and workforce development.

C.2.2. Retrofit Existing Pharmaceutical Facility(s) to Augment Current U.S.-based Capacity (Base Period):

Emergent shall execute the following tasks to establish the CIADM infrastructure:

- [**]

The following high level timeline/chart will be revised upon review and acceptance of the Integrated Master Project Plan component of the Overall Project Plan deliverable

[**]

C.2.2.1. [**] Facility Retrofit/Construction

Emergent shall perform architectural/engineering design, construction, material/equipment procurement, commissioning, qualification and validation necessary to expand ([**] foot print) the existing capacity at the [**] facility as outlined below and in accordance with the Technical Proposal.

The engineering firm that performed the detailed design of the [**] manufacturing areas associated with the current [**] facility retrofit also performed a preliminary site plan to provide a conceptual layout of an expansion to incorporate necessary features [**].

The expansion shall be connected to the existing [**] facility and provide expanded capacity of the existing utility systems. The manufacturing area shall have the same design features, segregation controls, and production capacities as the [**] existing manufacturing areas at the [**] facility. The warehouse portion shall be connected to the existing smaller warehouse space. The Preliminary Site Plan allows for the following:

[**]

C.2.2.1. [**] Pilot Plant Facility Retrofit

Emergent shall perform architectural/engineering design, construction, material/equipment procurement, commissioning, qualification and validation necessary to retrofit the pilot plant at its [**] facility ([**]) as outlined below and in accordance with the Technical Proposal. The pilot plant shall be the primarily location for core advanced development and manufacturing services and allow for eventual transfer of CBRN MCM candidates to the commercial-scale manufacturing facility in [**].

Emergent's [**] facility accommodates much of the company's project management, contract management, and product development activities. This [**] story building of approximately [**] is configured for both laboratory and office support. [**] level is dedicated to [**] with an

approximately [**] footprint. These laboratories include [**] laboratories. The [**] facility. Emergent's [**] facility is capable of [**]. Under this contract, the retrofitted Pilot Plant shall allow Emergent to scale-up and produce biologies and vaccines for clinical testing. The benefits include:

- Decrease in product timeline as there is no need to tech transfer for clinical production (e.g. the same personnel will be employed for both non-GMP process development and cGMP clinical production);
- Similar equipment as our commercial manufacturing which allows for ease of scale-up and production.

The space used for our pilot plant shall target:

[**]

The pilot plant shall be capable of [**].

The pilot plant shall contain [**] facility.

C.2.3. Provide Biopharmaceutical Production Surge Capacity:

Emergent's CIADM shall provide biopharmaceutical manufacturing surge capacity for emerging infectious diseases, pandemic influenza and other threats during public health emergencies utilizing flexible technologies that will augment the existing manufacturing infrastructure. The CIADM shall use cell, recombinant and molecular-based expression systems for the manufacture of pandemic influenza vaccine.

Emergent shall provide a surge capacity able to manufacture and deliver [**] finished doses of pandemic influenza vaccine within [**] of receipt of the virus reference strain, with the 1st doses available to the USG within [**] of receipt of the virus reference strain by using [**].

Emergent shall seek and follow FDA guidance for the FDA approval of the [**] facility as a manufacturing site for pandemic influenza vaccine surge manufacturing capacity by the end of the base period of the contract.

Emergent shall perform the following tasks aligned with established intellectual property (IP) milestone payment plan and the 'GO/NO GO DECISION POINTS FOR CONTINUING WITH THE [**] PANDEMIC INFLUENZA VACCINE' matrix contained within the Technical Proposal Appendix 16:

- Pandemic Influenza - Demonstration of feasibility of manufacture in disposable bioreactor
- Pandemic Influenza - Freedom to Operate (FTO) Analysis
- Pandemic Influenza - Paper Technical Transfer
- Pandemic Influenza - Assay Technical Transfer and Re-qualification
- Pandemic Influenza - Transfer of Small Scale
- Pandemic Influenza - Scale-up Confirmation

- Pandemic Influenza - BDS Engineering Lot 1
- Pandemic Influenza - BDS Engineering Lot 2
- Pandemic Influenza - BDS Engineering Lots Stability
- Pandemic Influenza - FDP Engineering Lot 2
- Pandemic Influenza - FDP Engineering Lot2 Stability
- Pandemic Influenza - BDS Consistency Lot 1
- Pandemic Influenza - BDS Consistency Lot 2
- Pandemic Influenza - BDS Consistency Lot 3
- Pandemic Influenza - BDS Consistency Lots Stability .
- Pandemic Influenza - FDP Consistency Lot 1
- Pandemic Influenza - FDP Consistency Lot 2
- Pandemic Influenza - FDP Consistency Lot 3
- Pandemic Influenza - FDP Consistency Lots Stability
- Pandemic Influenza - Rabbit Repeat-Dose Tox Study
- Pandemic Influenza - Clinical Bridging Study
- Pandemic Influenza - Type B Meeting
- Pandemic Influenza - Type C Meeting
- Pandemic Influenza - BLA Supplement

The following high level timeline/chart will be revised upon review and acceptance of the Integrated Master Project Plan component of the Overall Project Plan deliverable.

[**]

C.2.4. Pandemic Influenza Vaccine Readiness (Option)

After the Pandemic Influenza Vaccine is eligible for Emergency Use Authorization (EUA), Emergent shall conduct the activities necessary to maintain eligibility for an EUA. Once the facility has been FDA licensed for production of the Pandemic Influenza Vaccine, Emergent shall then conduct the activities necessary to maintain the license for the pandemic influenza vaccine manufacturing capability. The activities for maintaining the license will be determined as required by the FDA.

C.2.5 Implement Workforce Development (Base & Option):

Emergent shall supply biopharmaceutical oriented workforce development that is aligned with current regulatory guidelines via training programs with U.S.-based, accredited academic institutions or other industry recognized U.S.-based organizations that specialize in this area.

Emergent shall develop a plan for implementing their Workforce Development program during the first year of the base period of this contract. Full implementation of the Workforce Development program shall be offered as one (1) year renewable options.

Emergent’s proposed Workforce Development Program shall build on an established internship program to promote the development of the next generation of biopharmaceutical scientists and engineers. The current internship program was implemented [**] ago to 1) to identify talent

early on in their educational/career development and 2) to provide a much valued network of future employees in order to attract top talent. The program in place is administered by our Human Resources Department and encompasses all aspects of Medical Counter Measure (MCM) development and production including process development, engineering, manufacturing, non-clinical, clinical, regulatory, quality, business, finance, human resources and security. The current internship program is not integrated into a university curriculum. The internship program complements the curricula of the universities from which we hire interns. The internship program provides students with industry relevant skills and experience in an industry work environment as well as industry references to facilitate entry into the biotechnology workforce. It is a paid internship program with a pay structure for high school, undergraduate, graduate, and post-graduate positions. Emergent has an active outreach program with a number of universities to identify interns.

Emergent shall expand this program to increase the number of interns in scientific and engineering positions and to implement the program at Emergent Manufacturing Operations Baltimore LLC in parallel with commissioning and validation of the facility and licensure of the pandemic influenza vaccine candidate.

C.2.6. Management Approach:

Emergent shall provide the personnel and functions necessary to oversee, integrate, and coordinate all aspects of the SOW.

C.2.6.1. Integrated Master Project Plan: Emergent shall provide an Integrated Master Project Plan (including tabular and Gantt forms) to BARDA that clearly indicates the critical path to support the use of the product in the event of an EUA, and product approval. Attention shall be placed on the amount of time that will be needed by the USG (i.e. BARDA, FDA, CDC) for review of critical documentation. The Integrated Master Project Plan will be incorporated into the contract, and will be used to monitor performance of the contract.

C.2.6.1.1. Critical Path Milestones: The Integrated Master Project Plan shall outline key, critical path milestones, with “GO/NO GO” decision criteria (entrance and exit criteria for each phase of the project). The project plan should include, but not be limited to, milestones in manufacturing and necessary regulatory submissions.

C.2.6.1.2. Contract Work Breakdown Structure: Emergent shall further delineate the CWBS to [**] as part of their Integrated Master Project Plan. The CWBS shall be discernable and consistent. BARDA may require Emergent to furnish CWBS data at the work package level or at a lower level if there is significant complexity and risk associated with the task.

C.2.6.1.3. Risk Management Plan: Emergent 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 the appropriate plans to mitigate these risks. This plan should reference relevant WBS elements where appropriate.

C.2.6.1.4. Earned Value Management System Plan: Emergent shall use an Earned Value Management System (EVMS) in the management of this contract that is consistent with ANSI/EIA-STD-748 guidelines. EVMS shall be part of the Integrated Master Project Plan. Emergent shall submit a written summary of the management procedures that it will establish, maintain and use to comply with EVMS requirements to include the following topics:

- Integrated Baseline Review
- Integrated Master Schedule
- Earned Value Contract Performance Report (EV-CPR)

C.2.6.2. Subcontractor Management Plan: Emergent shall provide to the USG a subcontractor management plan that describes how, and by whom, all major subcontractors will be managed by the prime contractor (Emergent). A list of all subcontractors utilized in the performance of the proposed work shall be maintained by Emergent.

SECTION D - PACKAGING AND MARKING

D.1. METHOD OF DELIVERY

Unless otherwise specified by the Contracting Officer, delivery of the items to be furnished to the Government under this contract (including invoices) shall be made by commercial carrier, first class mail, overnight carrier, or e-mail.

D.2. PACKAGING AND SHIPPING

D.2.1. Packaging

As required, packaging of biopharmaceuticals and samples shall be consistent with the FDA-approved labeling and packaging at the time of manufacturing. Appropriate packaging and labeling changes may be required for product delivered under the Investigational New Drug (IND) and following product FDA marketing approval.

D.2.2. Shipping

Shipment of deliverables will be at the direction of the Contracting Officer.

D.3. REPORT DELIVERABLES

Unless otherwise specified by the Contracting Officer delivery of reports to be furnished to the Government under the resultant contract (including invoices), shall be addressed as follows:

[**]
Contracting Officer (CO)
HHS/OS/ASPR/AMCG
330 Independence Ave., SW
Rm [**]
Washington, DC 20201

[**]
Contracting Officer’s Representative (COR)
HHS/OS/ASPR/BARDA
330 Independence Ave, SW
Rm [**]
Washington, DC 20201

SECTION E - INSPECTION AND ACCEPTANCE

E.1. FAR CLAUSES

FAR Clause 52.252-2

Clauses Incorporated by Reference (FEB 1998)

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

FAR Clause	Title and Date
52.246-1	Contractor Inspection Requirements (Apr 1984)
52.246-2	Inspection of Supplies - Fixed Price (Aug 1996)
52.246-16	Responsibility of Supplies (Apr 1984)
52.246-12	Inspection of Construction (applies to Base Period) (Aug 1996)
52.246-15	Certificate of Conformance (applies to Base Period) (Apr 1984)

E.2. INSPECTION, ACCEPTANCE AND CONTRACT MONITORING

E.2.1. Inspection and Acceptance

The Contracting Officer or the duly authorized representative (who for purposes of this contract will be the Contracting Officer’s Representative) will inspect and accept materials and services to be delivered under the contract.

E.2.2. People in Plant

USG may place, for duration of its choosing, person(s) in the Contractor’s facility with a [**] advance notice to the Contractor. The Person(s) in Plant will observe, verify, inspect and survey the Contractor’s performance, environment and adherence to the Statement of Work and applicable regulations under this contract.

E.2.3. Audits

The Contractor shall allow for and provide requested information to support security, quality, regulatory, and cGMP audits conducted by USG on an ad hoc basis. The estimated frequency of audits under this paragraph is [**], unless an audit for cause is determined necessary at the discretion of the Contracting Officer. If the USG finds non-compliances or deficiencies during its audit(s) on firm fixed price line items, the Contractor, at its sole expense, shall take all necessary corrective action within a timely manner. In addition, the Contractor shall provide all

information requested by the USG, including the FDA, to facilitate a cGMP inspection at the time of production of vaccine lots.

SECTION F - DELIVERIES OR PERFORMANCE

F.1. PERIOD OF PERFORMANCE

The total period of performance (base and all option periods, if exercised) shall not exceed 25 years under this contract,

F.1.1. Base Period

The base period of performance is from the June 15, 2012 through June 14, 2020.

F.1.2. Option Periods

Each option period, if exercised, will extend the contract period of performance for an additional 12 month period. Each option will be exercised in accordance with FAR clause 52.217-09, entitled “Option to Extend the Term of the Contract (Mar 2000)”. Upon the Government’s failure to exercise an annual option period, all of the Contractor’s future performance obligations which would have otherwise arisen under this contract shall cease and/or be void and of no effect. Multiple option periods may be exercised at one time. However, no options shall be exercised before the Contractor has submitted a Description to the Contracting Officer as described in CLIN 0001 and secured the IP rights necessary to develop, manufacture, and sell the Pandemic Influenza Vaccine.

Depending when the Contractor is ready (and verified/approved by the Contracting Officer) to accept service task/delivery orders, option periods may be exercised during the base period. Under no circumstances shall the total period of performance (base period and all option periods) under this contract exceed twenty-five (25) years.

F.1.3. Period of Performance for Task Orders

Task orders related to ADM core services and warm-based influenza vaccine production will state their own deliverables and period of performance. The period of performance for task order issued pursuant to this contract are anticipated to run from one (1) to five (5) years.

F.2. TECHNICAL REPORT DELIVERABLES

The following is the Technical Report delivery schedule that shall be commensurate with the pricing schedule in Section B.

Deliverable	Quantity	Due Date
Monthly Technical Progress Report (12 of each per year - Base and Option Periods) (all CLINs)	Original - CO 1 Copy - COR 1 Electronic Copy - Sent to CO and COR	The initial Technical Progress Report due on/before [**]; thereafter, due on/before the [**] of the month or milestone following each reporting period. NOTE: A Technical Progress Report is not due when the Pinal Technical Closeout Report is due.
Executive Summary (12 of each per year - Base and Option Periods) (all CLINs)	Original - CO 1 Copy - COR 1 Electronic Copy - Sent to CO and COR	The initial Executive Summary due on/before [**]; thereafter, due on/before the [**] of the month or milestone following each reporting period. NOTE: An Executive Summary is not due when the Final Technical Closeout Report is due.
Facility(s) Construction/ Retrofit - Overall Project Plan (CLIN 0002.1 & 0002.2)	Original - CO 2 Copies - COR 1 Electronic Copy - Sent to CO and COR	Within [**] after contract award.
Regulatory and Clinical Bridging Study Plan (CLIN 0002.3)	Original - CO 2 Copies - COR 1 Electronic Copy - Sent to CO and COR	Within [**] after contract award.
Facility Operation Feasibility Plan (CLIN 0002.1 & 0002.2)	Original - CO 2 Copies - COR 1 Electronic Copy - Sent to CO and COR	Within [**] after contract award.
Detailed Manufacturing Facility Plan (CLIN 0002.1 & 0002.2)	Original - CO 2 Copies - COR 1 Electronic Copy - Sent to CO and COR	Within [**] after contract award.
Final Security Plan (CLIN 0002.5)	Original - CO 2 Copies - COR 1 Electronic Copy - Sent to CO and COR	Within [**] after contract award.
Commissioning and Validation Plan (CLIN 0002.1 & 0002.2)	Original - CO 2 Copies - COR 1 Electronic Copy - Sent to CO and COR	Within [**] after contract award.
Operating Plan and Facility Cost Model (CLIN 0002.1 & 0002.2)	Original - CO 2 Copies - COR 1 Electronic Copy - Sent to CO and COR	Within [**] of completion of the base period of the contract.
Final Technical Closeout Report (CLIN 0002.3)	Original - CO 2 Copies - COR 1 Electronic Copy - Sent to CO and COR	Within [**] of completion of last acceptable consistency/validation lot in the new and/or retrofitted facility(s).
Development/ Manufacturing Summary Report (Task Order #/Delivery Order#____)(all CLINs)	Original - CO 1 Copy - COR 1 Electronic Copy - Sent to CO and COR	Within [**] of completion of a specific Task Order/Delivery Order, a written report summarizing the campaign, cost of goods, and release documents must be submitted.

F.3. MEETINGS

F.3.1. Monthly Teleconferences

The Contractor shall participate in monthly teleconferences with USG to discuss the performance of the contract. At the discretion of the Contracting Officer, additional [**] teleconferences may

be scheduled. The Contractor shall keep meeting minutes and forward a finalized copy to the Contracting Officer and COR for approval within [**] after each teleconference, or as otherwise authorized by the Contracting Officer.

F.3.2. Periodic Site Visits

The Contractor shall accommodate for periodic site visits by USG on an ad hoc basis. The estimated frequency of visits under this paragraph is [**]. The Contractor shall keep minutes and forward a finalized copy to the Contracting Officer and COR for approval within [**] after each site visit, or as otherwise authorized by the Contracting Officer.

F.3.3. Quarterly Site Visits

The Contractor shall provide formal presentations summarizing all work accomplished in the previous calendar quarter at the Contractor's site on a quarterly basis. The Contractor shall keep meeting minutes and forward a finalized copy to the Contracting Officer and COR for approval within [**] after each site visit, or as otherwise authorized by the Contracting Officer.

F.4. PLACE AND METHOD OF DELIVERY

F.4.1. Delivery of contract deliverables specified under Section F.2 and Section F.3 shall be F.O.B. destination, within consignee's premises.

F.4.2. Unless otherwise specified, deliveries shall be Monday through Friday (excluding Federal Holidays) between the hours of 8:30 AM and 5:00 PM EST only. Contract deliverables scheduled for delivery on a Federal holiday shall be made the following business day.

F.4.3. Deliveries shall be made to the address specified in Section D.3.

F.5. CONTRACT CLAUSES

FAR Clause 52.252-2

CONTRACT CLAUSES INCORPORATED BY REFERENCE (Feb 1998)

This contract incorporates one or more solicitation 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/these address(es):

www.acquisition.gov
http://www.hhs.gov/oamp/policies/

FAR CLAUSES	TITLE	DATE
52.211-10	Commencement, Prosecution and Completion of Work	APR 1984
52.242-15	Stop Work Order - Alternate I (AUG 1984)	AUG 1989
52.247-35	F.O.B. Destination, Within Consignee's Premises	APR 1984
52.211-17	Delivery of Excess Quantities	SEP 1989
52.242-17	Government Delay of Work	APR 1984

SECTION G-CONTRACT ADMINISTRATION DATA

G.1. CONTRACT ADMINISTRATION

G.1.1. Contracting Officer

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.

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; or (5) otherwise change any terms and conditions of this contract.

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 any stipulation of this contract.

G.1.2. Contracting Officer's Representative (COR)

The Contracting Officer's Representative (COR), to be named prior to contract award, will assist the contracting officer is resolving technical issues that arise during performance. The Government Contracting Officer's Representative is not authorized to change any of the terms and conditions of the contract. Changes shall be made only by the Contracting Officer by proper written modification(s) to the contract. Any changes in Contracting Officer's Representative delegation will be made by the Contracting Officer in writing with a copy being furnished to the Contractor.

G.2. PAYMENTS AND INVOICING

G.2.1. Payment By Electronic Funds Transfer - Central Contractor Registration (OCT 2003)

The Government shall use electronic funds transfer to the maximum extent possible when making payments under this contract. FAR 52.232-34 (May 1999), Payment by Electronic Funds Transfer in Section I, requires the contractor to designate in writing a financial institution for receipt of electronic funds transfer payments.

The Contractor shall make the designation by submitting the form titled “ACH Vendor/Miscellaneous Payment Enrollment Form” to the address indicated below. In cases where the Contractor has previously provided such designation, i.e., pursuant to a prior contract/order, and has been enrolled in the program, the form may not be required unless the designation has changed.

The completed form shall be submitted prior to contract award, but no later than [**] before an invoice is submitted, to the Contracting Officer at the address in Section G.2.2.1.

G.2.2. Invoice Submission

G.2.2.1. The Contractor shall submit an original and two hard copies as well as one electronic copy (address to be provided at a later date) of contract invoices to the address shown below:

HHS/OS/ASPR/AMCG
Attn.: Contracting Officer
330 Independence Ave., S.W.
Room G640
Washington, D.C. 20201

G.2.2.2. The Contractor agrees to include (as a minimum) the following information on each invoice:

(1) Contractor’s Name & Address
(2) Contractor’s Tax Identification Number (TIN)
(3) Contract Number and delivery/task order (if applicable)
(4) Invoice Number
(5) Invoice Date
(6) Contract Line Item Number
(7) Quantity
(8) Unit Price & Extended Amount for each line item
(9) Total Amount of Invoice
(10) Name, title and telephone number of person to be notified in the event of a defective invoice
(11) Payment Address, if different from the information in (c)(1).
(12) Any additional backup information required to justify the invoice.

G.2.2.3. See Section J for additional invoicing instructions.

G.3. MISCELLANEOUS CONTRACT ADMINISTRATION

G.3.1. Evaluation Of Contractor Performance (Service) (JAN 2000)

(a) *Purpose:* In accordance with FAR 42.1502 - Policy, the contractor's performance will be periodically evaluated by the government in order to provide current information for source selection purposes. These evaluations will therefore be marked "Source Selection Information."

(b) *Performance Evaluation Period:* The contractor's performance will be evaluated at least [**].

(c) *Evaluators:* The performance evaluation will be completed jointly by the Contracting Officer's Representative and the Contracting Officer.

(d) *Performance Evaluation Factors:* The contractor's performance will be evaluated in accordance with an approved Contractor Performance Evaluation Report which will be discussed and agreed to at the kick-off meeting.

(e) *Contractor Review:* A copy of the evaluation will be provided to the contractor as soon as practicable after completion of the evaluation. The contractor shall submit comments, rebutting statements, or additional information to the Contracting Officer within [**] after receipt of the evaluation.

(f) *Resolving Disagreements between the Government and the Contractor:* Disagreements between the parties regarding the evaluation will be reviewed at a level above the Contracting Officer. The ultimate conclusion on the performance evaluation is a decision of the contracting agency. Copies of the evaluation, Contractor's response, and review comments, if any, will be retained as part of the evaluation.

(g) *Release of Contractor Performance Evaluation Information:* The completed evaluation will not be released to other than Government personnel and the contractor whose performance is being evaluated. Disclosure of such information could cause harm both to the commercial interest of the Government and to the competitive position of the contractor being evaluated, as well as impede the efficiency of Government operations,

(h) *Source Selection Information*: Departments and agencies may share past performance information with other Government departments and agencies when requested to support future award decisions. The information may be provided through interview and/or by sending the evaluation and comment document to the requesting source selection official.

(i) *Retention Period*: The agency will retain past performance information for a maximum period of [**] after completion of contract performance for the purpose of providing source selection information for future contract awards.

G.3.2. Contract Communications/Correspondence

The Contractor shall identify all correspondence, reports, and other data pertinent to this contract by imprinting thereon the contract number (and delivery/task order if applicable) from Page 1 of the contract.

G.3.3. 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 advanced notice to the Contracting Officer, provided that no such notice is required to comply with any law, rule, regulation, court ruling or similar order; for submission to any government entity; for submission to any securities exchange on which the Contractor's (or its parent corporation's) securities may be listed for trading; or to third parties relating to securing, seeking, establishing, or maintaining regulatory or other legal approvals or compliance, financing and capital raising activities, or mergers, acquisitions, or other business transactions.

G.3.4. Reporting Matters Involving Fraud, Waste, And Abuse

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in BARDA-funded programs 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 **Htips@os.dhhs.gov** and the mailing address is:

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

G.4. INDIRECT COST RATES

Pending the establishment of final indirect cost rates which shall be negotiated based on audit of actual costs as provided in Subpart 42.7 of the Federal Acquisition Regulation, the Contractor shall be reimbursed for allowable indirect costs hereunder at the billing rate listed below.

This INDIRECT COST provision does not operate to waive the LIMITATION OF FUNDS Clause. Tire Contractor's audited final indirect costs are allowable only insofar as they do not cause the Contractor to exceed the total estimated costs for performance of the contract.

BILLING RATES

Fringe benefits at [**]%, applied to a base sum of total direct labor, development overhead at [**]%, applied at a base sum of total direct labor plus fringe benefits and G&A at [**]% applied to a modified base that excludes subcontracts, materials and equipment.

The provisional labor and indirect rates negotiated under this contract for billing purposes shall remain in effect until revised rates have been approved in writing by the Contracting Officer. The Contractor shall request new provisional billing rates in writing. Such request shall delineate the current and proposed rates to be used.

G.5. ACCOUNTING AND APPROPRIATION DATA

BASE PERIOD:

CLIN 0001: $ [**] (NOT TO EXCEED)
CLIN 0002: $[**] (NOT TO EXCEED)

Accounting and Appropriation Data: 2012 1994020 32201

OPTION PERIODS:

All option periods are Subject to the Availability of Funds (FAR 52.232.18)

Accounting & Appropriation data will be listed on task/delivery orders issued pursuant to this contract

SECTION H - Special Contract Requirements

H.1. PROHIBITION ON THE USE OF APPROPRIATED FUNDS FOR LOBBYING ACTIVITIES (JUL 1999)

The Contractor is hereby notified of the restrictions on the use of HHS funding for lobbying of Federal, State and Local legislative bodies.

Section 1352 of Title 10, United Stated Code (Public Law 101-121, effective 12/23/89), among other things, prohibits a recipient of a Federal contract, grant, loan, or cooperative agreement from using appropriated funds (other than profits from a federal contract) to pay any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with any of the following covered Federal actions: the awarding of any Federal contract; the making of any Federal grant; the making of any Federal loan; the entering into of any cooperative agreement; or the modification of any Federal contract, grant, loan, or cooperative agreement. For additional information of prohibitions against lobbying activities, see FAR Subpart 3.8 - Limitations on the Payment of Funds to Influence Federal Transactions and FAR Clause 52.203-12 (Sep 2007).

In addition, the current HHS Appropriations Act provides that no part of any appropriation contained in this Act shall be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes; for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support, or defeat legislation pending before the Congress, or any State or Local legislature except in presentation to the Congress; or any State or Local legislative body itself. The current HHS Appropriations Act also provides that no part of any appropriation contained in this Act shall be used to pay the salary or expenses of any contract or grant recipient, or agent acting for such recipient, related to any activity designed to influence legislation or appropriations pending before the Congress, or any State or Local legislature.

H.2. REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

The Representations, Certifications and Other Statements of Offerors submitted by the Contractor dated July 6, 2011 through July 12, 2012 are hereby incorporated by reference, with the same force and effect as if they were given in full text.

H.3. LABORATORY LICENSE REQUIREMENTS

The Contractor shall comply with all applicable requirements of Section 353 of the Public Health Service Act (Clinical Laboratory Improvement Act as amended) Section 353 of the Public Health Service Act (Clinical Laboratory Improvement Act as amended). This requirement shall also be included in any subcontract for services under the contract.

H.4. DISSEMINATION OF INFORMATION

No information related to data obtained under this contract shall be released or publicized without the prior written consent of the Contracting Officer, whose approval shall not be unreasonably withheld, conditioned, or delayed, provided that no such consent is required to comply with any law, rule, regulation, court ruling or similar order; for submission to any government entity for submission to any securities exchange on which the Contractor's (or its parent corporation's) securities may be listed for trading; or to third parties relating to securing, seeking, establishing or maintaining regulatory or other legal approvals or compliance, financing and capital raising activities, or mergers, acquisitions, or other business transactions.

H.5. ACCESS AND DISPOSITION OF DATA

The government shall have physical and electronic access to all documentation and data generated under this contract, including: all Contractor efforts; Subcontractor efforts; communications and correspondence with regulatory agencies and bodies to include all audit observations, inspection reports, and all Contractor commitments and responses. Contractor shall provide the government with an electronic copy of all correspondence with the FDA within [**] of receipt. The Government shall have unlimited rights to all animal and human data funded under this RFP. The contractor shall keep copies of all data required by the FDA relevant to this contract for the time specified by the FDA.

H.6. INCORPORATION OF TECHNICAL PROPOSAL

The Contractor's Technical Proposal included in its Proposal dated April 13, 2012 or as revised by the Final Proposal Revision dated April 30, 2012, submitted in response to RFP-11-SOL-00011 is hereby incorporated into the contract by reference. The Contractor shall perform the work substantially as set forth in the technical proposal. Any revisions to the Technical Proposal that would significantly alter the technical approach must be approved in writing by the Contracting Officer. Within [**] after contract award, the Contractor is required to deliver to the Contracting Officer a consolidated copy of their full Technical Proposal. In the event of a conflict between Section C, SOW, and the Contractor's Technical Proposal, Section C will take precedence.

H.7. PROTECTION OF HUMAN SUBJECTS

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 1) 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 2) the individual will assume responsibility for safeguarding the human subjects involved. The OHRP web site is: http://www.hhs.gov/ohrp. The Contractor further agree to provide certification at least [**] that the Institutional Review Board has reviewed and approved the procedures that involve human subjects in accordance with 45 CFR Part 46 and the Assurance of Compliance.

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.

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.

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 the OHRP, terminate the contract in whole or in part, and the name of the Contractor may be removed from the list of those contractors with approved HHS Human Subject Assurances.

H.8. INFORMATION ON COMPLIANCE WITH ANIMAL CARE REQUIREMENTS

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

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

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

The Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) http://www.aaalac.org is a professional organization that inspects and evaluates

programs of animal care for institutions at their request. Those that meet the high standards are given the Accredited status. As of the 2002 revision of the PHS Policy, the only accrediting body recognized by PHS is the AAALAC. While AAALAC Accreditation is not required to conduct biomedical research, it is highly desirable. AAALAC uses the *Guide* as its primary evaluation tool. It also uses the *Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching.* It is published by the Federated of Animal Science Societies http://www.fass.org.

H.9. 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 OLAW, establishing appropriate policies and procedures to ensure the humane care and use of live vertebrate animals involved in research activities supported by the PHS. The PHS Policy stipulates that an applicant organization, whether domestic or foreign, bears responsibility for the humane care and use of animals in PHS-supported research activities. Also, the PHS policy defines “animal” as “any live, vertebrate animal used, or intended for use, in research, research training, experimentation, biological testing or for related purposes.” This Policy implements and supplements the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training, and requires that institutions use the Guide for the Care and Use of Laboratory Animals as a basis for developing and implementing an institutional animal care and use program. This Policy does not affect applicable State or Local laws or regulations that impose more stringent standards for the care and use of laboratory animals. All institutions are required to comply, as applicable, with the Animal Welfare Act as amended (7 USC 2131 et. seq.) and other Federal statutes and regulations relating to animals. These documents are available from the Office of Laboratory Animal Welfare, National Institutes of Health, Bethesda, MD 20892, (301) 496-7163. See http://grants.nih.gov/grants/olaw/olaw.htm.

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

H.10. CARE OF LIVE VERTEBRATE ANIMALS

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.

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.

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 USDA (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.

If at any time during performance of this contract, the Contracting Officer determines, in consultation with the OLAW, 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 contractors with approved PHS Animal Welfare Assurances.

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 NIH at (301) 594-2289.

H.11. APPROVAL OF REQUIRED ASSURANCE BY OLAW

Under governing regulations, federal funds that are administered by the Department of Health and Human Services, Office of Biomedical Advanced Research and Development Authority (BARDA) shall not be expended by the Contractor for research involving live vertebrate animals, nor shall live vertebrate animals be involved in research activities by the Contractor under this award unless a satisfactory assurance of compliance with 7 U.S.C. 2316 and 9 CFR Sections 2.25-2.28 is submitted within [**] 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 that do not directly involve live vertebrate animals (i.e. are clearly severable and independent from those activities that do involve live vertebrate animals) may be conducted by the Contractor or individual performance sites pending OLAW approval of their respective assurance of compliance with 7 U.S.C. 2316 and 9 CFR Sections 2.25-2.28. Additional information regarding OLAW may be obtained via the Internet.

H.12. ACKNOWLEDGEMENT OF FEDERAL FUNDING

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

H.13. MANUFACTURING STANDARDS

The Current Good Manufacturing Practice (cGMP) regulations (21 CFR Parts 210-211) will be the standard to be applied for manufacturing, processing and packaging of this 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 product and such failure results in a material adverse effect on the safety, and purity of the product (a material failure) as identified by the FDA, then the Contractor shall have [**] from the time such material failure is identified to institute a comprehensive plan and obtain approval by the Contracting Officer to cure such material failure. If the Contractor fails to take such an action within the [**] period, then the contract may be terminated.

H.14. PROHIBITION ON CONTRACTOR INVOLVEMENT WITH TERRORIST ACTIVITIES

The Contractor acknowledges that U.S. Executive Orders and Laws, including but not limited to Executive Order 13224 and Public Law 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.

H.15. KEY PERSONNEL

The personnel specified in this contract are considered to be essential to the work being performed hereunder. Prior to diverting any of the specified individuals to other programs, the Contractor shall notify the Contracting Officer at least [**] in advance and shall submit justification (including proposed substitutions possessing the same or greater qualifications/experience as the individual being substituted) in sufficient detail to permit evaluation of the impact on the program. No diversion shall be made by the Contractor without the written

consent of the Contracting Officer; provided that the Contracting Officer may ratify in writing that such diversion and such ratification shall constitute the consent of the Contracting Officer required by this clause. The contract may be modified from time to time during the course of the contract to either add or delete key personnel as appropriate.

Contractor Key Personnel:

Name	Position
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]

H.16. REGISTRATION WITH THE SELECT AGENT PROGRAM FOR WORK INVOLVING THE POSSESSION, USE, AND/OR TRANSFER OF SELECT BIOLOGICAL AGENTS OR TOXINS

Work involving select biological agents or toxins shall not be conducted under this contract until the Contractor and any affected subcontractor(s) are granted a certificate of registration or are authorized to work with the applicable select agents.

For prime or subcontract awards to domestic institutions who possess, use, and/or transfer Select Agents under this contract, the institution must complete registration with BARDA, or APHIS, as applicable, before performing work involving Select Agents, in accordance with 42 CFR 73. No Government funds can be used for work involving Select Agents, as defined in 42 CFR 73, if the final registration certificate is denied.

For prime or subcontract awards to foreign institutions who possess, use, and/or transfer Select Agents under this contract, the institution must provide information satisfactory to the Government that a process equivalent to that described in 42 CFR 73 (http://www.cdc.gov/od/sap/docs/42cfr73.pdf) for U.S. institutions is in place and will he administered on behalf of all Select Agent work sponsored by these funds before using these funds for any work directly involving the Select Agents. The contractor must provide information addressing the following key elements appropriate for the foreign institution: safety, security, training, procedures for ensuring that only approved/appropriate individuals have access to the Select Agents, and any applicable laws, regulations and policies equivalent to 42 CFR 73. The Government will assess the policies and procedures for comparability to the U.S. requirements described in 42 CFR Part 73. When requested by the contracting officer, the contractor shall provide key information delineating any laws, regulations, policies, and procedures applicable to the foreign institution for the safe and secure possession, use, and transfer of Select Agents. This includes summaries

of safety, security, and training plans, and applicable laws, regulations, and policies. For the purpose of security risk assessments, the contractor must provide the names of all individuals at the foreign institution who will have access to the Select Agents and procedures for ensuring that only approved and appropriate individuals have access to Select Agents under the contract.

Listings of HHS Select Agents and toxins, biologic agents and toxins, and overlap agents or toxins as well as information about the registration process, can be obtained on the Select Agent Program Web site at http://www.cdc.gov/od/sap/.

H.17. SECURITY

The work to be performed under this contract will involve access to sensitive Biomedical Advanced Research and Development Authority (BARDA) program information. Upon contract award, the Program Protection Officer (PPO) will review the Draft Security Plan (submitted as part of the Contractor's Technical Proposal) in detail and submit comments within [**] to the Contracting Officer (CO) to be forwarded to the Contractor. The Contractor shall review the Draft Security Plan comments, and if changes are required, submit a Final Security Plan to the U.S. Government within [**] after receipt of the Program Protection Officer's (PPO) comments. The Final Security Plan shall include a timeline for compliance of all the required security measures. Upon completion of initiating all security measures, the Contractor shall supply to the Contracting Officer a letter certifying compliance to the elements outlined in the Final Security Plan. The execution of the work under this contract shall be in accordance with the approved Final Security Plan. As outlined above, the content of the Final Security Plan shall be a continuation of the Draft Security Plan submitted as part of the Contractor's Technical Proposal. The Security Plan should address facilities providing core ADM services for CBRN medical countermeasures and influenza vaccine manufacturing. Therefore, at a minimum, the Final Security Plan shall address the following items:

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

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

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

Information Technology Security Policies and Procedures including but not limited to: Intrusion detection and prevention systems; Encryption systems; Identification of sensitive information/

media; Passwords; Removable media; Laptop policy; Media access control/determination; Secure storage; System document control; System backup; System disaster recovery.

The following instruction/intent shall be incorporated:

> Security Reporting Requirement - Violations of established security protocols shall be reported to the Contracting Officer (CO) and Contracting Officer's Representative (COR) upon discovery. The Contractor will investigate violations to determine the cause, extent, loss or compromise of sensitive program information, and corrective actions taken to prevent future violations. Contracting Officer will determine if the severity of the violation requires further U.S. Government (USG) intervention.

H.18. FAR 52.234-4 - EARNED VALUE MANAGEMENT SYSTEM (JULY 2006)

(a) The Contractor shall use an earned value management system (EVMS) that has been determined by the Cognizant Federal Agency (CFA) to be compliant with the guidelines in ANSI/EIA Standard - 748 (current version at the time of award) to manage this contract. If the Contractor's current EVMS has not been determined compliant at the time of award, see paragraph (b) of this clause. The Contractor shall submit reports in accordance with the requirements of this contract.

(b) If, at the time of award, the Contractor's EVM System has not been determined by the CFA as complying with EVMS guidelines or the Contractor does not have an existing cost/schedule control system that is compliant with the guidelines in ANSI/EIA Standard - 748 (current version at time of award), the Contractor shall—

(1) Apply the current system to the contract; and
(2) Take necessary actions to meet the milestones in the Contractor's EVMS plan approved by the Contracting Officer.

(c) The Government will conduct an Integrated Baseline Review (IBR). If a pre-award IBR has not been conducted, a post award IBR shall be conducted within [**] after contract award.

(d) The Contracting Officer may require an IBR at—

(1) Exercise of significant options; or
(2) Incorporation of major modifications.

(e) Unless a waiver is granted by the CFA, Contractor proposed EVMS changes require approval of the CFA prior to implementation. The CFA will advise the Contractor of the acceptability of such changes within [**] after receipt of the notice of proposed changes from the Contractor. If the advance approval requirements are waived by the CFA, the Contractor shall disclose EVMS changes to the CFA at least [**] prior to the effective date of implementation.

(f) The Contractor shall provide access to all pertinent records and data requested by the Contracting Officer or a duly authorized representative as necessary to permit Government

surveillance to ensure that the EVMS conforms, and continues to conform, with the performance criteria referenced in paragraph (a) of this clause.

(g) The Contractor shall require the subcontractors specified below to comply with the requirements of this clause:

_____
_____
_____
_____

(End of clause)

H.19. INTERACTIONS WITH REGULATORY AGENCIES

The obligations set forth in this paragraph shall apply to the contractor and any subcontract at any tier thereunder as applicable under this Contract and any Task Orders issued hereunder.

(a) The Contractor shall prepare and submit initial draft minutes and final accepted minutes of all formal meetings with U.S. regulatory agencies, to include FDA, to BARDA.

(b) The Contractor shall prepare and submit initial draft minutes and the final accepted minutes of all informal meetings with U.S. regulatory agencies, to include FDA, to BARDA.

(c) The Contractor shall forward the dates and times of all scheduled meetings with U.S. regulatory agencies, to include FDA, to BARDA and make arrangements for appropriate BARDA staff to attend such U.S. regulatory agencies meetings.

(d) The Contractor shall provide BARDA the opportunity to review and comment upon any documents to be submitted to U.S. regulatory agencies. The contractor shall provide BARDA with [**], or such shorter period as may be practicable in time-sensitive situations, to review and provide comments to the Contractor prior to its submittal to U.S. regulatory agencies.

(e) The Contractor shall furnish all findings of U.S. regulatory agencies inspections, including FDA Form 482 and 483 inspection notice and observations and Establishment Inspection Reports (EIR) pertinent to the contract, to BARDA within [**] of receipt.

(f) The Contractor shall notify the USG of all site visits/audits by U.S. regulatory agencies, to include FDA, within [**] of agency personnel’s arrival.

(g) The Contractor shall include the USG in all scheduled meetings and teleconferences with U.S. regulatory agencies.

H.20. SUBCONTRACTING PROVISIONS

(a) Small Business Subcontracting Plan

1. The Small, Small Disadvantaged and Women Owned Small Business Subcontracting Plan, dated April 13, 2012 is attached hereto and made a part of this contract.

2. The failure of any Contractor or subcontractor to comply in good faith with FAR Clause 52.219-8 entitled “Utilization of Small Business Concerns” incorporated in this contract and the attached Subcontracting Plan (Attachment 5) will be a material breach of such contract or subcontract and subject to the remedies reserved to the Government under FAR Clause 52.219-16 entitled, “LIQUIDATED DAMAGES--SUBCONTRACTING PLAN.”

(b) Subcontracting Reports

As of October 28, 2005 the Electronic Subcontract Reporting System (eSRS) is available for use by all civilian agencies and their contractors at www.esrs.gov. The eSRS will eliminate both standard forms Subcontracting Reports for Individual Contracts (formerly SF 294) and Summary Subcontract Reports (formerly SF 295) paper submissions, and contractors will now submit all their reports electronically to a single, government wide system. The eSRS is the latest system under the umbrella of the Integrated Acquisition Environment (IAE).

All civilian agency contractors must now submit their Summary Subcontract Reports into the eSRS.

No contractors of any agency will be required to submit the Subcontracting Reports for Individual Contracts into the eSRS for fiscal year 2004.

No contractors of any agency will be required to submit mid-year reports for fiscal year 2005 (normally due April 30 for the period ended March 31st) into the eSRS. This exemption applies to both the Subcontracting Reports for Individual Contracts and the Summary Subcontract Reports.

Frequently Asked Questions and other information are available on the eSRS website at www.esrs.gov. If you have any further questions or comments, you may contact the SBA at eSRS@sba.gov or the IAE at integrated.acquistion@gsa.gov.

H.21. EPA ENERGY STAR REQUIREMENTS

In compliance with Executive Order 12845 (requiring Agencies to purchase energy efficient computer equipment) all microcomputers, including personal computers, monitors, and printers that are purchased using Government funds in performance of a contract shall be equipped with or meet the energy efficient low-power standby feature as defined by the EPA Energy Star program unless the equipment always meets EPA Energy Star efficiency levels. The microcomputer, as configured with all components, must be Energy Star compliant. This low-power feature must already be activated when the computer equipment is delivered to the agency and be of equivalent functionality of similar power managed models. If the equipment will be used on a local area network, the vendor must provide equipment that is fully compatible with

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

H.22. RESERVED

H.23. LIABILITY PROTECTION

The Secretary's Declaration for Public Readiness and Emergency Preparedness Act (PREP Act), Section 319F-3 of the Public Health Service Act, 42 U.S.C. 247d-6d, Coverage for Vaccines Against Pandemic Influenza A Viruses and Influenza A Viruses With Pandemic Potential effective February 29, 2012 (as amended) applies to this contract, subject to the terms and conditions of such Declaration and any amendments thereto.

In the event the Contractor delivers vaccine under this contract which is not covered by the aforementioned declaration because of the expiration of the aforementioned declaration and any renewals or amendments thereof, the Government agrees that the medical countermeasure delivered by the Contractor under this contract will not be administered for use in humans, unless the Secretary executes a new declaration in accordance with section 319F-3(b) of the Public Health Service Act, 42 U.S.C. 247d-6d, or renews or amends the an existing declaration, to provide that such medical countermeasures delivered under this contract are covered countermeasures to which section 319F-3(a) applies subject to the terms and conditions of the Declaration and any amendments thereto, and the new or renewed or amended declaration provides the Contractor at least the same coverage as the aforementioned declaration.

H.24. CONFIDENTIALITY OF INFORMATION

The following information is covered by HHSAR 352.224-70, Privacy Act (JAN 2006): Data obtained from human subjects.

H.25. NATIONAL ENVIRONMENTAL POLICY ACT OF 1969 (NEPA)

HHS is required to follow the National Environmental Policy Act of 1969 (NEPA), implementing regulations, and executive orders; for any project that utilizes federal funds or federal property. The Offeror/Awardee must submit, as required by the Contracting Officer, an assessment of the impact of the construction and/or renovation of facilities in the proposed project on the human environment pursuant to section 102(2)(c) of NEPA and its implementing regulations, as well as a report showing the results of tests for environmental hazards present in the facility, ground water, and soil. HHS will provide advice and assistance to the Offeror/Awardee, as necessary, concerning review procedures; evaluate the results of the review; and make the final decision on environmental impact as required by NEPA.

H.26. FACILITY

In consideration for the agreements and mutual benefits herein provided, upon receipt of the Occupancy Permit(s) (as defined under paragraph B.3.2.) or termination for convenience of this contract by the Government, whichever occurs earlier, all rights and title to the facility shall pass

to the Contractor, and the Government shall retain no right of ownership in the facility and related equipment to be funded under this contract. Notwithstanding the foregoing, in the event this contract is terminated for the default of the Contractor, all rights and title to tire facility shall similarly pass to the Contractor; provided, however that the Contractor shall thereupon be obligated to pay to the Government, as liquidated damages for such transfer of rights and title and not as a penalty, an amount in proportion to the cost share agreement between the Contractor and the Government. That is, up to [**] percent ([**]%) for a new facility, and up to [**] percent ([**]%) of a retrofitted facility (See Pricing Schedule under CLIN 0002). Appraisal of the facility for purposes of determining the compensation due the Government under this Subsection shall be performed in accordance with the then most current version of the Uniform Appraisal Standards for Federal Land Acquisitions. Notwithstanding any term or provision contained in this contract to the contrary, the obligations of the parties under this Subsection shall survive the termination of this contract, including, but not limited to any termination for default.

SECTION I - CONTRACT CLAUSES

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

52.252-2 CLAUSES INCORPORATED BY REFERENCE (Feb 1998)

This contract incorporates one or more 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/these address(es):

www.acquisition.gov
http ://farsite.hill.af.mil/vffar1.htm

I.1.1. Clauses Applicable all of the Contract (Base Period and Options)

FAR CLAUSE	*TITLE*	*DATE*
52.202-1	Definitions	JAN 2012
52.203-3	Gratuities	APR 1984
52.203-5	Covenant Against Contingent Fees	APR 1984
52.203-6	Restrictions on Subcontractor Sales to the Government	SEP 2006
52.203-7	Anti-Kickback Procedures	OCT 2010
52.203-8	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity	JAN 1997
52.203-10	Price or Fee Adjustment for Illegal or Improper Activity	JAN 1997
52.203-12	Limitation on Payments to Influence Certain Federal Transactions	OCT 2010
52.203-13	Contractor Code of Business Ethics and Conduct	APR 2010
52.203-14	Display of Hotline Poster(s) [handwritten note: applicable to subs if ---- executed]	DEC 2007
52.204-4	Printed or Copied Double-Sided on Postconsumer Fiber Content Paper	MAY 2011
52.204-7	Central Contractor Registration	FEB 2012
52.204-8	Annual Representations and Certifications	FEB 2012
52.204-9	Personal Identity Verification of Contractor Personnel	JAN 2011
52.204-10	Reporting Executive Compensation and First-Tier Subcontract Awards	FEB 2012
52.209-6	Protecting the Government’s Interest When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment	DEC 2010
52.215-2	Audit and Records - Negotiation	OCT 2010
52.215-8	Order of Precedence - Uniform Contract Format	OCT 1997

FAR CLAUSE	***TITLE***	***DATE***
52.215-10	Price Reduction for Defective Certified Cost or Pricing Data	AUG 2011
52.215-11	Price Reduction for Defective Certified Cost or Pricing Data - Modifications	AUG 2011
52.215-12	Subcontractor Cost or Pricing Data	OCT 2010
52.215-13	Subcontractor Cost or Pricing Data - Modifications	OCT 2010
52.215-15	Pension Adjustments and Asset Reversions	OCT 2010
52.215-17	Waiver of Facilities Capital Cost of Money	OCT 1997
52.215-18	Reversion or Adjustment of Plans for Postretirement Benefits (PRB) Other Than Pensions	JUL 2005
52.215-19	Notification of Ownership Changes	OCT 1997
52.215-21	Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data - Modifications	OCT 2010
52.215-23	Limitations on Pass-Through Charges	OCT 2009
52.216-7	Allowable Cost and Payment	JUN 2011
52.216-18	Ordering	OCT 1995
52.216-19	Order Limitations (See Section B.2.3.1.3)	OCT 1995
52.215-22	Indefinite Quantity	OCT 1995
52.219-8	Utilization of Small Business Concerns	JAN 2011
52.219-9	Small Business Subcontracting Plan - Alternate II (OCT 2001)	JAN 2011
52.219-16	Liquidated Damages - Subcontracting Plan	JAN 1999
52.219-25	Small Disadvantaged Business Participation Program - Disadvantaged Status and Reporting	DEC 2010
52.222-1	Notice to the Government of Labor Disputes	FEB 1997
52.222-3	Convict Labor	JUN 2003
52.222-21	Prohibition of Segregated Facilities	FEB 1999
52.222-26	Equal Opportunity	MAR 2007
52.222-29	Notification of Visa Denial	JUN 2003
52.222-35	Equal Opportunity for Veterans	SEP2010
52.222-36	Affirmative Action for Workers with Disabilities	OCT 2010
52.222-37	Employment Reports Veterans	SEP 2010
52.222-50	Combating Trafficking in Persons	FEB 2009
52.223-1	Biobased Product Certification	DEC 2007
52.223-2	Affirmative Procurement of Biobased Products under Service and Constructions Contracts	DEC 2007
52.223-4	Recovered Material Certification	MAY 2008
52.223-6	Drug-Free Workplace	MAY 2001

52.223-9	Estimate of Percentage of Recovered Material Content for EPA-Designated Items	MAY 2008
52.223-15	Energy Efficiency and Energy Consuming Products	DEC 2007
52.225-1	Buy American Act - Supplies	FEB 2009

FAR CLAUSE	***TITLE***	***DATE***
52.225-13	Restrictions on Certain Foreign Purchases	JUN 2008
52.226-1	Utilization of Indian Organizations and Indian-Owned Economic Enterprises	JUN 2000
52.227-1	Authorization and Consent - Alternate I (APR 1984)	DEC 2007
52.227-2	Notice and Assistance Regarding Patent and Copyright Infringement	DEC 2007
52.227-3	Patent Indemnity	APR 1984
52.227-14	Rights in Data - General	DEC 2007
52.227-16	Additional Data Requirements	JUN 1987
52.230-2	Cost Accounting Standards	OCT 2010
52.230-6	Administration of Cost Accounting Standards	JUN 2010
52.232-9	Limitation on Withholding of Payments	APR 1984
52.232-17	Interest	OCT 2010
52.232-23	Assignment of Claims	JAN 1986
52.232-25	Prompt payment - Alternate I (FEB 2002)	OCT 2008
52.232-33	Payment by Electronic Funds Transfer - Central Contractor Registration	OCT 2003
52.233-1	Disputes - Alternate I (DEC 1991)	JUL 2002
52.233-3	Protest after Award - Alternate I (JUN 1985)	AUG 1996
52.233-4	Applicable Law for Breach of Contract Claim	OCT 2004
52.243-6	Change Order Accounting	APR 1984
52.242-13	Bankruptcy	JUL 1995
52.244-2	Subcontracts	OCT 2010
52.244-5	Competition in Subcontracting	DEC 1996
52.244-6	Subcontracts for Commercial Items	DEC 2010
52.245-1	Government Property	APR 2012
52.245-9	Use and Charges	APR 2012
52.246-23	Limitation of Liability	FEB 1997
52.248-1	Value Engineering	OCT 2010
52.249-2	Termination for Convenience of the Government (Fixed-Price) (Applicable to only the FFP items under the contract)	APR 2012
52.253-1	Computer Generated Forms	JAN 1991

I.1.2. Clauses Applicable to Design and Construction (Base Period)

FAR CLAUSE	***TITLE***	***DATE***

FAR CLAUSE	***TITLE***	***DATE***
42.211-5	Material Requirements	AUG 2000
52.216-12	Cost-Sharing Contract - No Fee [handwritten note – N/A to subs]	APR1984
52.222-6	Davis-Bacon Act	JUL 2005
52.222-7	Withholding of Funds	FEB 1988
52.222-8	Payrolls and Basic Records	JUN 2010
52.222-9	Apprentices and Trainees	JUL 2005
52.222-10	Compliance with Copeland Act Requirements	FEB 1988
52.222-11	Subcontracts (Labor Standards)	JUL 2005
52.222-12	Contract Termination - Debarment	FEB 1988
52.222-13	Compliance with Davis-Bacon and Related Act Regulations	FEB 1988
52.222-15	Certification of Eligibility	FEB 1988
52.222-16	Approval of Wage Rates	FEB 1988
52.222-19	Child Labor - Cooperation with Authorities and Remedies	APR 2012
52.222-27	Affirmative Action Compliance Requirements for Construction	FEB 1999
52.223-17	Affirmative Procurement of EPA-designated Items in Services and Construction Contracts	MAY 2008
52.225-11	Buy American Act--Construction Materials Under Trade Agreements	APR 2012
52.225-12	Notice of Buy American Act Requirements - Construction Materials under Trade Agreements	APR 2012
52.227-4	Patent Indemnity - Construction Contracts	DEC 2007
52.228-2	Additional Bond Security	OCT 1997
52.228-14	Irrevocable Letter of Credit	DEC 1999
52.228-15	Performance and Payment Bonds - Construction *(Total value of performance and Payment Bonds shall he for the total Government's share of construction costs.)*	OCT 2010
52.229-3	Federal, State, and Local Taxes	APR 2003
52.232-16	Progress Payments	APR 2012
52.232-27	Prompt Payment for Construction Contracts	OCT 2008
52.236-2	Differing Site Conditions	APR 1984
52.236-3	Site Investigation and Conditions Affecting the Work	APR 1984
52.236-5	Material and Workmanship	APR 1984
52.236-6	Superintendence by the Contractor	APR 1984
52.236-7	Permits and Responsibilities	NOV 1991
52.236-12	Cleaning Up	APR 1984
52.236-13	Accident Prevention	NOV 1991
52.236-15	Schedules for Construction Contracts	APR 1984
52.236-18	Work Oversight in Cost-Reimbursement Construction Contracts	APR 1984

FAR CLAUSE	***TITLE***	***DATE***
52.236-19	Organization and Direction of the Work	APR 1984
52.236-21	Specifications and Drawings for Construction - Alternate I (APR 1984)	FEB 1997
52.236-23	Responsibility of the Architect-Engineer Contractor	APR 1984
52.236-24	Work Oversight in Architect-Engineer Contracts	APR 1984
52.236-25	Requirements for Registration of Designers	JUN 2003
52.236-26	Preconstruction Conference	FEB 1995
52.243-4	Changes	JUN 2007
52.248-2	Value Engineering - Architect-Engineering	MAR 1990
52.248-3	Value Engineering - Construction	OCT 2010
52.249-6	Termination (Cost-Reimbursement) (Applicable to the cost-share.) [handwritten note – N/A to subs]	MAY 2004
52.249-14	Excusable Delays	APR 1984

NOTE: There is no fee in a cost-share contract

I.1.3. Clauses Applicable to Option Periods (FFP and CPFF)

FAR CLAUSE	***TITLE***	***DATE***
52.215-14	Integrity of Unit Prices	OCT 2010
52.216-8	Fixed Fee	JUN 2011
52.222-4	Contract Work Hours and Safety Standards Act - Overtime Compensation (Applicable to Readiness CLIN)	JUL 2005
52.222-41	Service Contract Act of 1965 (Applicable to Readiness CLIN)	NOV 2007
52.227-14	Rights in Data—General -- Alternate I (DEC 2007)	DEC 2007
52.232-20	Limitation of Cost	APR 1984
52.232-22	Limitation of Funds	APR 1984
52.242-1	Notice of Intent to Disallow Costs	APR 1984
52.242-3	Penalties for Unallowable Costs	MAY 2001
52.242-4	Certification of Final Indirect Costs	JAN 1997
52.243-2	Changes - Cost-Reimbursement - Alternate I (APR 1984)	AUG 1987
52.249-6	Termination (Cost-Reimbursement) (Applicable to the CPFF portion of the contract)	MAY 2004
52.249-14	Excusable Delays-	APR 1984

DOL Wage Determinations under the Service Contract Act and Davis-Bacon Act are included as an attachment to this contract

I.1.3. Clauses Incorporated in Full Text

I.1.3.1. Clauses Applicable to the Entire Contract

FAR 52.209-9

Updates of Publicly Available Information Regarding Responsibility Matters (Feb 2012)

(a) The Contractor shall update the information in the Federal Awardee Performance and Integrity Information System (FAPIIS) on a [**] basis, throughout the life of the contract, by posting the required information in the Central Contractor Registration database via https://www.acquisition.gov.

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

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

(i) Government personnel and authorized users performing business on behalf of the Government; or
(ii) The Contractor, when viewing data on itself; and

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

(i) Past performance reviews required by subpart 42.15;
(ii) Information that was entered prior to April 15, 2011; or
(iii) Information that is withdrawn during the 14-calendar-day waiting period by the Government official who posted it in accordance with paragraph (c)(1) of this clause.

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

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

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

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

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

FAR Clause 52.217-8

Option to Extend Services (NOV 1999)

The Government may require continued performance of any services within the limits and at the rates specified in the contract. These rates may be adjusted only as a result of revisions to prevailing labor rates provided by the Secretary of Labor. The option provision may be exercised more than once, but the total extension of performance hereunder shall not exceed [**]. The Contracting Officer may exercise the option by written notice to the Contractor within [**].

FAR Clause 52.217-9

Option to Extend the Term of the Contract (MAR 2000)

(a) The Government may extend the term of this contract by written notice to the Contractor within [**]; provided that the Government gives the Contractor a preliminary written notice of its intent to extend at least [**] before the contract expires. The preliminary notice does not commit the Government to an extension.

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

(c) The total duration of this contract, including the exercise of any options under this clause, shall not exceed 25 years.

I.1.3.2. Clauses Applicable to the Base Period of the Contract

FAR Clause 52.222-2

Payment for Overtime Premiums (JUL 1990)

(a) The use of overtime is authorized under this contract if the overtime premium - does not exceed $0 or the overtime premium is paid for work -

(1) Necessary to cope with emergencies such as those resulting from accidents, natural disasters, breakdowns of production equipment, or occasional production bottlenecks of a sporadic nature;
(2) By indirect-labor employees such as those performing duties in connection with administration, protection, transportation, maintenance, standby plant protection, operation of utilities, or accounting;
(3) To perform tests, industrial processes, laboratory procedures, loading or unloading of transportation conveyances, and operations in flight or afloat that are continuous in nature and cannot reasonably be interrupted or completed otherwise; or
(4) That will result in lower overall costs to the Government.

(b) Any request for estimated overtime premiums that exceeds the amount specified above shall include all estimated overtime for contract completion and shall -

(1) Identify the work unit; *e.g.*, department or section in which the requested overtime will be used, together with present workload, staffing, and other data of the affected unit sufficient to permit the Contracting Officer to evaluate the necessity for the overtime;
(2) Demonstrate the effect that denial of the request will have on the contract delivery or performance reasons schedule;
(3) Identify the extent to which approval of overtime would affect the performance or payments in connection with other Government contracts, together with identification of each affected contract; and
(4) Provide why the required work cannot be performed by using multishift operations or by employing additional personnel.

FAR 52.223-19

Compliance with Environmental Management Systems (MAY 2011)

The Contractor’s work under this contract shall conform with all operational controls identified in the applicable agency or facility Environmental Management Systems and provide monitoring and measurement information necessary for the Government to address environmental performance relative to the goals of the Environmental Management Systems.

(End of clause)

FAR Clause 52.236-22

Design Within Funding Limitations. (APR 1984)

(a) The Contractor shall accomplish the design services required under this contract so as to permit the award of a contract, using standard Federal Acquisition Regulation procedures for the construction of the facilities designed at a price that does not exceed the estimated construction contract price as set forth in paragraph (c) below. When bids or proposals for the construction contract are received that exceed the estimated price, the contractor shall perform such redesign and other services as are necessary to permit contract award within the funding limitation. These

additional services shall be performed at no increase in the price of this contract. However, the Contractor shall not be required to perform such additional services at no cost to the Government if the unfavorable bids or proposals are the result of conditions beyond its reasonable control.

(b) The Contractor will promptly advise the Contracting Officer if it finds that the project being designed will exceed or is likely to exceed the funding limitations and it is unable to design a usable facility within these limitations. Upon receipt of such information, the Contracting Officer will review the Contractor's revised estimate of construction cost. The Government may, if it determines that the estimated construction contract price set forth in this contract is so low that award of a construction contract not in excess of such estimate is improbable, authorize a change in scope or materials as required to reduce the estimated construction cost to an amount within the estimated construction contract price set forth in paragraph (c) below, or the Government may adjust such estimated construction contract price. When bids or proposals are not solicited or are unreasonably delayed, the Government shall prepare an estimate of constructing the design submitted and such estimate shall be used in lieu of bids or proposals to determine compliance with the funding limitation.

(c) The estimated construction contract price for the project described in this contract is $[**] (final negotiated construction price minus contractors cost share).

I.1.3.3. Clauses Applicable to all Option Periods (FFP and CPFF)

FAR Clause 52.227-11

Patent Rights -- Ownership by the Contractor (DEC 2007)

(a) As used in this clause--

"Invention" means any invention or discovery that is or may be patentable or otherwise protectable under title 35 of the U.S. Code, or any variety of plant that is or may be protectable under the Plant Variety Protection Act (7 U.S.C. 2321, et seq.)

"Made" means—

(1) When used in relation to any invention other than a plant variety, the conception or first actual reduction to practice of the invention; or
(2) When used in relation to a plant variety, that the Contractor has at least tentatively determined that the variety has been reproduced with recognized characteristics.

"Nonprofit organization" means a university or other institution of higher education or an organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1954 (26 U.S.C. 501(c)) and exempt from taxation under section 501(a) of the Internal Revenue Code (26 U.S.C. 501(a)), or any nonprofit scientific or educational organization qualified under a State nonprofit organization statute.

"Practical application" means to manufacture, in the case of a composition of product; to practice, in the case of a process or method; or to operate, in the case of a machine or system

and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are, to the extent permitted by law or Government regulations, available to the public on reasonable terms.

“Subject invention” means any invention of the Contractor made in the performance of work under this contract.

(b) Contractor’s rights.

(1) Ownership. The Contractor may retain ownership of each subject invention throughout the world in accordance with the provisions of this clause.

(2) License.

(i) The Contractor shall retain a nonexclusive royalty-free license throughout the world in each subject invention to which the Government obtains title, unless the Contractor fails to disclose the invention within the times specified in paragraph (c) of this clause. The Contractor’s license extends to any domestic subsidiaries and affiliates within the corporate structure of which the Contractor is a part, and includes the right to grant sublicenses to the extent the Contractor was legally obligated to do so at contract award. The license is transferable only with the written approval of the agency, except when transferred to the successor of that part of the Contractor’s business to which the invention pertains.

(ii) The Contractor’s license may be revoked or modified by the agency to the extent necessary to achieve expeditious practical application of the subject invention in a particular country in accordance with the procedures in FAR 27.302(i)(2) and 27.304-1(f).

(c) Contractor’s obligations. (1) The Contractor shall disclose in writing each subject invention to the Contracting Officer within [**] after the inventor discloses it in writing to Contractor personnel responsible for patent matters. The disclosure shall identify the inventor(s) and this contract under which the subject invention was made. It shall be sufficiently complete in technical detail to convey a clear understanding of the subject invention. The disclosure shall also identify any publication, on sale (i.e., sale or offer for sale), or public use of the subject invention, or whether a manuscript describing the subject invention has been submitted for publication and, if so, whether it has been accepted for publication. In addition, after disclosure to the agency, the Contractor shall promptly notify the Contracting Officer of the acceptance of any manuscript describing the subject invention for publication and any on sale or public use.

(2) The Contractor shall elect in writing whether or not to retain ownership of any subject invention by notifying the Contracting Officer within [**] of disclosure to the agency. However, in any case where publication, on sale, or public use has initiated the 1-year statutory period during which valid patent protection can be obtained in the United States, the period for election of title may be shortened by the agency to a date that is no more than [**] prior to the end of the statutory period.

(3) The Contractor shall file either a provisional or a nonprovisional patent application or a Plant Variety Protection Application on an elected subject invention within [**] after election. However, in any case where a publication, on sale, or public use has initiated the 1-year statutory period during which valid patent protection can be obtained in the United States, the Contractor shall file the application prior to the end of that statutory period. If the Contractor files a provisional application, it shall file a nonprovisional application within [**] of the filing of the provisional application. The Contractor shall file patent applications in additional countries or international patent offices within either [**] of the first filed patent application (whether provisional or nonprovisional) or [**] from the date permission is granted by the Commissioner of Patents to file foreign patent applications where such filing has been prohibited by a Secrecy Order.

(4) The Contractor may request extensions of time for disclosure, election, or filing under paragraphs (c)(1), (c)(2), and (c)(3) of this clause.

(d) Government's rights--(1) Ownership. The Contractor shall assign to the agency, on written request, title to any subject invention--

(i) If the Contractor fails to disclose or elect ownership to the subject invention within the times specified in paragraph (c) of this clause, or elects not to retain ownership; provided, that the agency may request title only within [**] after learning of the Contractor's failure to disclose or elect within the specified times.

(ii) In those countries in which the Contractor fails to file patent applications within the times specified in paragraph (c) of this clause; provided, however that if the Contractor has filed a patent application in a country after the times specified in paragraph (c) of this clause, but prior to its receipts of the written request of the agency, the Contractor shall continue to retain ownership in that country.

(iii) In any country in which the Contractor decides not to continue the prosecution of any application for, to pay the maintenance fees on, or defend in reexamination or opposition proceeding on, a patent on a subject invention.

(2) License. If the Contractor retains ownership of any subject invention, the Government shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice, or have practiced for or on its behalf, the subject invention throughout the world.

(e) Contractor action to protect the Government's interest. (1) The Contractor shall execute or have executed and promptly deliver to the agency all instruments necessary to--

(i) Establish or confirm the rights the Government has throughout the world in those subject inventions in which the Contractor elects to retain ownership; and

(ii) Assign title to the agency when requested under paragraph (d) of this clause and to enable the Government to obtain patent protection and plant variety protection for that subject invention in any country.

(2) The Contractor shall require, by written agreement, its employees, other than clerical and nontechnical employees, to disclose promptly in writing to personnel identified as responsible for the administration of patent matters and in the Contractor's format, each subject invention in order that the Contractor can comply with the disclosure provisions of paragraph (c) of this clause, and to execute all papers necessary to file patent applications on subject inventions and to establish the Government's rights in the subject inventions. The disclosure format should require, as a minimum, the information required by paragraph (c)(1) of this clause. The Contractor shall instruct such employees, through employee agreements or other suitable educational programs, as to the importance of reporting inventions in sufficient time to permit the filing of patent applications prior to U.S. or foreign statutory bars.

(3) The Contractor shall notify the Contracting Officer of any decisions not to file a nonprovisional patent application, continue the prosecution of a patent application, pay maintenance fees, or defend in a reexamination or opposition proceeding on a patent, in any country, not less than [**] before the expiration of the response or filing period required by the relevant patent office.

(4) The Contractor shall include, within the specification of any United States nonprovisional patent or plant variety protection application and any patent or plant variety protection certificate issuing thereon covering a subject invention, the following statement, "This invention was made with Government support under (identify the contract) awarded by (identify the agency). The Government has certain rights in the invention."

(f) Reporting on utilization of subject inventions. The Contractor shall submit, on request, periodic reports no more frequently than [**] on the utilization of a subject invention or on efforts at obtaining utilization of the subject invention that are being made by the Contractor or its licensees or assignees. The reports shall include information regarding the status of development, date of first commercial sale or use, gross royalties received by the Contractor, and other data and information as the agency may reasonably specify. The Contractor also shall provide additional reports as may be requested by the agency in connection with any march-in proceeding undertaken by the agency in accordance with paragraph (h) of this clause. The Contractor also shall mark any utilization report as confidential/proprietary to help prevent inadvertent release outside the Government. As required by 35 U.S.C. 202(c)(5), the agency will not disclose that information to persons outside the Government without the Contractor's permission.

(g) Preference for United States industry. Notwithstanding any other provision of this clause, neither the Contractor nor any assignee shall grant to any person the exclusive right to use or sell any subject invention in the United States unless the person agrees that any products embodying the subject invention or produced through the use of the subject invention will be manufactured

substantially in the United States. However, in individual cases, the requirement for an agreement may be waived by the agency upon a showing by the Contractor or its assignee that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States, or that under the circumstances domestic manufacture is not commercially feasible.

(h) March-in rights. The Contractor acknowledges that, with respect to any subject invention in which it has retained ownership, the agency has the right to require licensing pursuant to 35 U.S.C. 203 and 210(c), and in accordance with the procedures in 37 CFR 401.6 and any supplemental regulations of the agency in effect on the date of contract award.

(i) Special provisions for contracts with nonprofit organizations. If the Contractor is a nonprofit organization, it shall--

(1) Not assign rights to a subject invention in the United States without the written approval of the agency, except where an assignment is made to an organization that has as one of its primary functions the management of inventions, provided, that the assignee shall be subject to the same provisions as the Contractor;

(2) Share royalties collected on a subject invention with the inventor, including Federal employee co-inventors (but through their agency if the agency deems it appropriate) when the subject invention is assigned in accordance with 35 U.S.C. 202(e) and 37 CFR 401.10;

(3) Use the balance of any royalties or income earned by the Contractor with respect to subject inventions, after payment of expenses (including payments to inventors) incidental to the administration of subject inventions for the support of scientific research or education; and

(4) Make efforts that are reasonable under the circumstances to attract licensees of subject inventions that are small business concerns, and give a preference to a small business concern when licensing a subject invention if the Contractor determines that the small business concern has a plan or proposal for marketing the invention which, if executed, is equally as likely to bring the invention to practical application as any plans or proposals from applicants that are not small business concerns; provided, that the Contractor is also satisfied that the small business concern has the capability and resources to carry out its plan or proposal. The decision whether to give a preference in any specific case will be at the discretion of the Contractor.

(5) Allow the Secretary of Commerce to review the Contractor’s licensing program and decisions regarding small business applicants, and negotiate changes to its licensing policies, procedures, or practices with the Secretary of Commerce when the Secretary’s review discloses that the Contractor could take reasonable

steps to more effectively implement the requirements of paragraph (i)(4) of this clause.

(j) Communications. Shall be addressed to the Contracting Officer.

(k) Subcontracts.

(1) The Contractor shall include the substance of this clause, including this paragraph (k), in all subcontracts for experimental, developmental, or research work to be performed by a small business concern or nonprofit organization.

(2) The Contractor shall include in all other subcontracts for experimental, developmental, or research work the substance of the patent rights clause required by FAR Subpart 27.3.

(3) At all tiers, the patent rights clause must be modified to identify the parties as follows: references to the Government are not changed, and the subcontractor has all rights and obligations of the Contractor in the clause. The Contractor shall not, as part of the consideration for awarding the subcontract, obtain rights in the subcontractor's subject inventions.

(4) In subcontracts, at any tier, the agency, the subcontractor, and the Contractor agree that the mutual obligations of the parties created by this clause constitute a contract between the subcontractor and the agency with respect to the matters covered by the clause; provided, however, that nothing in this paragraph is intended to confer any jurisdiction under the Contract Disputes Act in connection with proceedings under paragraph (h) of this clause.

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

HHSAR CLAUSE	***TITLE***	***DATE***
352.201-70	Paperwork Reduction Act	JAN 2006
352.202-1	Definitions	JAN 2006
352.203-70	Anti-Lobbying	MAR 2012
352.216-70	Additional Cost Principles	JAN 2006
352.222-70	Contractor Cooperation in Equal Employment Opportunity Investigations	JAN 2010
352.223-70	Safety and Health	JAN 2006
352.224-70	Privacy Act	JAN 2006
352.227-70	Publications and Publicity	JAN 2006
352.228-7	Insurance - Liability to Third Persons	DEC 1991
352.231-70	Salary Rate Limitation	MAR 2012
352.231-71	Pricing of Adjustments -	JAN 2001
352.233-71	Litigation and Claims	JAN 2006
352.242-70	Key Personnel MJ/v >	JAN 2006
352.242-73	Withholding of Contract Payments	JAN 2006
352.242-74	Final Decisions on Audit Findings	APR 1984

SECTION J - LIST OF ATTACHMENTS

Attachment #	Title	Pages
1	Definitions	1
2	Core Services Matrix	1
3	Disclosure of Lobbying Activities	2
4	Points of Contact	1
5	Small Business Subcontracting Plan, dated April 13, 2012	18
6	Invoice/Financing Request Instructions	2
7	Protection of Human Subjects OF310	1
8	Wage Determinations (Service Contract Act & Davis- Bacon Act)	10
9	Contractor’s Technical Proposal, dated April 13,	836

ATTACHMENT #1 (REVISED 6-6-11)
DEFINITIONS

COMMERCIAL ACTIVITY: For the purpose of this contract, commercial activity is defined as all efforts performed by the Contractor that are not specifically supporting the Statement of Work in this contract, including a resulting Task Order or Delivery Order.

FLEXIBLE MANUFACTURING: Flexible manufacturing is the capability to modify equipment, facilities and processes to meet changing requirements. It could include disposables, modular skids, etc.

NEW FACILITY: A new facility (new construction) would be a greenfield site or a new building constructed on an existing campus.

RETROFITTED FACILITY: A retrofitted facility (renovated) would involve an existing pharmaceutical structure requiring modifications to architecture, equipment, piping, HVAC, etc. to meet the stated requirements.

US-BASED: US-based is defined as within the United States of America and its territories and possessions.

SUCCESSFUL INITIATION OF PHASE I TRIAL: A successful initiation of a Phase I trial would be at the point where the first patient has been placed on the study.

BIOPHARMACEUTICALS: Biopharmaceutical is defined as vaccines and other therapeutic biologies manufactured by biotechnology methods involving live organisms/bio-processing [e.g. vaccines, monoclonal antibodies, rDNA proteins] that would be regulated by the FDA.

AVAILABLE TO THE USG: Doses of pandemic influenza vaccine will be considered “available to the USG” after completion of internal quality release by the manufacturer and completion of final packaging and movement into the distribution system under manufacturers control, so that the doses are ready to ship upon CBER release.

PRINCIPAL INVESTIGATOR (PI): For the purpose of this solicitation and resulting contract awards, the PI shall be an officer, director, owner, partner, or a person having primary management or supervisory responsibilities that is duly and legally authorized to represent and speak on behalf of the prime contractor and has overarching leadership to direct personnel in executing all aspects of the statement of work in an efficient and effective manner. The PI will be the main contact with HHS regarding all scientific, process and technology related issues.

PROJECT MANAGER (PM): For the purpose of this solicitation and resulting contract awards, the PM shall be a person having primary management or supervisory responsibilities that is duly and legally authorized to represent and speak on behalf of the prime contractor. The PM will be the main contact with HHS regarding all scheduling, deliverables and other business-related aspects of the contract.

UNENCUMBERED ACCESS: Unencumbered Access is defined as a means of entering, visiting, using, and exiting without being obstructed.