AWARD/CONTRACT

1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700) ▶ RATING: N/A | PAGE 1 OF PAGES 49

2. CONTRACT *(Proc. Inst. Ident.)* NO.: HHSO100201400005C

3. EFFECTIVE DATE: See Block 20C

4. REQUISITION/PURCHASE REQUEST/PROJECT NO.: BAA-BARDA-11-100-SOL-00021 REQ. No. OS107514

5. ISSUED BY CODE: N/A

HHS/OS/ASPR/AMCG
330 INDEPENDENCE AVE S.W., RM G640
WASHINGTON, D.C. 20201

6. ADMINISTERED BY *(If other than Item 5)* CODE: N/A

See Block 5

7. NAME AND ADDRESS OF CONTRACTOR *(No., street, county, State and ZIP Code)*

PHILIPS RESPIRONICS, INC.
1010 MURRY RIDGE LANE
MURRYSVILLE, PA 15668-8525

DUNS: [redacted]

CODE | FACILITY CODE

8. DELIVERY

☐ FOB ORIGIN ☒ OTHER *(See below)*

9. DISCOUNT FOR PROMPT PAYMENT

N/A

10. SUBMIT INVOICES *(4 copies unless otherwise specified)* TO THE ADDRESS SHOWN IN ▶ ITEM: See Section G

11. SHIP TO/MARK FOR CODE: N/A

See Block 5

12. PAYMENT WILL BE MADE BY CODE: N/A

See Block 5

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

Appropriation: No Year CAN: 1994032 Accounting Info.: 2014.1994032.25505 Object Class: 25505
Amount: $11,820,069 Approp.: 75-X-0140
Appropriation: 2014 CAN: 1994039 Accounting Info.: 2014.1994039.25505 Object Class: 25505
Amount: $2,000,000 Approp.: 75-14-0140

15A. ITEM NO.	15B. SUPPLIES/SERVICES	15C. QUANTITY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT
	See Section B				
				15G. TOTAL AMOUNT OF CONTRACT	$13,820,069

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X	B	SUPPLIES OR SERVICES AND PRICES/COSTS	3-7			PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACH.	
X	C	DESCRIPTION/SPECS./WORK STATEMENT	8-13	X	J	LIST OF ATTACHMENTS	48
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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* TWO *copies to issuing office.)* Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any continuation sheets for the consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the following documents: (a) this award/contract, (b) the solicitation, if any, and (c) such provisions, representations, certifications, and specifications, as are attached or incorporated by reference herein. *(Attachments are listed herein.)*

18. ☐ SEALED-BID AWARD *(Contractor is not required to sign this document.)*

Your bid on Solicitation Number _____ including the additions or changes made by you which additions or changes are set forth in full above, is hereby accepted as to the terms listed above and on any continuation sheets. This award consummates the contract which consists of the following documents: (a) the Government's solicitation and your bid, and (b) this award/contract. No further contractual document is necessary. (Block 18 should be checked only when awarding a sealed-bid contract.)

19A. NAME AND TITLE OF SIGNER *(Type or Print)*

20A. NAME OF CONTRACTING OFFICER: Pedro Godinez

19B. NAME OF CONTRACTOR | 19C. DATE SIGNED

BY _____
(Signature of person authorized to sign)

20B. UNITED STATES OF AMERICA | 20C. DATE SIGNED

BY _____
(Signature of Contracting Officer)

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Prescribed by GSA - FAR (48 CFR) 53.214(a)

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SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

The purpose of this contract is for the development of an Advanced All Hazard Stockpile Ventilator (AAHSV) which at the end of the contract period (36 months) will be a Food and Drug Administration (FDA) 501(k) cleared ventilator with testing and certification to ensure compliance to the standards set in Appendix 10 of the Statement of Work in Section C. The contract includes an Option for New Model Initial production of 10,000 ventilators and accessories as indicated in Section B, Article B.3.

ARTICLE B.2. TYPE OF CONTRACT AND ESTIMATED COST

a. This Award is a hybrid contract with COST REIMBURSEMENT type and FIRM FIXED PRICE contract line items (CLINS). More specifically, this is for a Cost-Reimbursement (CR) Base CLIN for Research and Development, with a 36-month BASE period; plus a 21-month Firm Fixed Priced (FFP) Option CLIN for New Model Initial Production Ventilators.

b. The estimated cost of this Multiple-Year Non-Severable **Cost Reimbursement** (CR) contract is $13,820,069.

Cost Reimbursement Item	Description of Item	Total Price (CR)
CLIN 0001 Base (Article B.2)	Development of an FDA 501(k) cleared Enhanced Ventilator (EV)	$13,820,069

c. The total amount for this contract shall not exceed $13,820,069 and the Government will not be responsible for any Contractor incurred costs that exceed this amount unless a modification to the contract is signed by the Contracting Officer which expressly increases this amount. For further provisions on funding, see the LIMITATION OF COSTS clause referenced in Part II, Contract Clauses.

d. It is estimated that the currently allotted funds will cover performance of the contract through September 14, 2017. Refer to **Article F.1. Period of Performance**.

e. The Contractor shall maintain records of all contract costs and such records shall be subject to the Audit and Records-Negotiation and Final Decisions on Audit Findings clauses of the General Clauses.

ARTICLE B.3. OPTION PRICES (Firm Fixed Price (FFP) CLIN)

a. Unless the Government exercises its option pursuant to the option clause referenced in ARTICLE I.5. ADDITIONAL CONTRACT CLAUSES, this contract consists only of the Base Period specified in the Statement of Work as defined in SECTIONS C and F, for the price set forth in ARTICLE B.2. of this contract.

b. Pursuant to FAR Clause 52.217-7, Option for Increased Quantity-Separately Priced Line Item set forth in Part II, Section I. of this contract, the Government may, by unilateral contract modification, require the Contractor to perform additional option set forth in the Statement of Work and also defined in Sections C and F of the contract. If the Government exercises this option, notice must be given at least 90 days prior to the expiration date of this contract. Delivery will commence on an agreed upon schedule if an option is exercised by the Government. The price of this contract will be increased as set forth in paragraph c., below.

c. Upon the delivery and acceptance of the Option Items described in SECTION C of the contract and identified in the schedule of charges below, the Government shall pay the Contractor on a Firmed Fixed Price basis the unit prices set forth below:

Option Fixed Price Items	Description of Option Item	Quantity (Units)	Unit Price	Total Price (FFP)
CLIN 0002 **OPTION ONE**	New Model Initial Production Fully Kitted FDA-Approved AAHSV Ventilator plus Rugged Basic Pulse Oximeter and Colorimetric Co2 Intubation Monitor	10,000	$3,280	**$32,800,000**

Payment schedule for the Option Items:

Milestone	Total
Complete manufacture and packaging and delivery of first 2,500 units	$ 8,200,000
Complete manufacture and packaging and delivery of second 2,500 units	$ 8,200,000
Complete manufacture and packaging and delivery of third 2,500 units	$ 8,200,000
Complete manufacture and packaging and delivery of fourth 2,500 units	$ 8,200,000
TOTAL	**$ 32,800,000**

The Contractor can submit Final Milestone Payment request when ALL Option Items have been inspected and accepted at the place of delivery by Government personnel and this acceptance has been verified by the Contracting Officer and Contracting Officer's Representative. Acceptance includes delivery of all documentation in relation to the Option Items, including certifications, manuals, and guides.

ARTICLE B.4. ADVANCE UNDERSTANDINGS

1. **Invoices:** Cost and Personnel Reporting:

   See Articles G.4 and G.5 and the Attachment #2 for detailed requirements for Invoicing.

2. **Publications:** Any manuscript or scientific meeting abstract containing data generated under this contract must be submitted to the Contracting Officer and Contracting Officer's Representative for review no less than thirty (30) Calendar days for manuscripts and fifteen (15) Calendar days for abstracts before submission for public presentation or publication. Contract support shall be acknowledged in all such publications. A "publication" is defined as an issue of printed material offered for distribution or any communication or oral presentation of information. Refer to Article H.14.

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

4. **Man-in-Plant:** With seven (7) days advanced notice to the Contractor, in writing from the Contracting Officer, the Government may place a man-in-plant in the Contractor's facility. The individual shall be subject to the Contractor's policies and procedures regarding security and facility access at all times while in the Contractor's facility.

5. **Confidentiality of Information:** The following information is covered by HHSAR Clause 352.224-70, Confidentiality of Information (January 2006): Data obtained from human subjects.

6. **Subcontracts and Consultants:** Award of any FFP subcontract or FFP consulting agreement, or any cost reimbursement subcontract or consulting agreement shall not proceed without the prior written consent of the Contracting Officer via a Contracting Officer Authorization (COA) Letter upon review of the supporting documentation required by FAR Clause 52.244-2, Subcontracts. After receiving written consent of the subcontract by the Contracting Officer, a copy of the signed, executed subcontract and consulting agreement shall be provided to the Contracting Officer within ten (10) days.

7. **Confidential Treatment of Sensitive Information:** The Contractor shall guarantee strict confidentiality of any information/data of a sensitive nature that is provided to the Contractor by the Government during the performance of the contract. The Government has determined that the information/data that the Contractor will be provided during the performance of the contract is of a sensitive nature.

   Disclosure of information/data that is sensitive in nature, in whole or in part, by the Contractor can only be made after the Contractor receives prior written approval from the Contracting Officer. Whenever the Contractor is uncertain with regard to the proper handling of information/data under the contract, the Contractor shall obtain a written determination from the Contracting Officer.

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

   Contractor may disclose information/data of a sensitive nature provided by the Government to the extent that such disclosure is: (a) made in response to a valid order of a court of competent jurisdiction or other supra-national, federal, national, regional, state, provincial or local governmental or regulatory body of competent jurisdiction; provided, however, that the Contractor shall first have given immediate notice to the Government and give the Government a reasonable opportunity to quash such order and/or to obtain a protective order requiring that the information/data of a sensitive nature that is the subject of such order be held in confidence by such court or agency or, if disclosed, be used only for the purposes for which the order was issued. The Government has the right to elect any and all remedies available to it in responding to any such order or similar legal document; and provided further that if a disclosure order is not quashed or a protective order is not obtained, the information/data disclosed in response to such court or governmental order shall be limited to that information which is legally required to be disclosed in response to such court or governmental order; (b) made by the Contractor to the Regulatory Authorities as required in connection with any filing, application or request for Regulatory Approval; provided, however, that all such information will be provided in advance to the Contracting Officer for review and reasonable measures shall be taken to assure confidential treatment of such information/data.

ARTICLE B.5. PROVISIONS APPLICABLE TO DIRECT COSTS

a. **Items Unallowable Unless Otherwise Provided**

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

(1) Conferences and Meetings;
(2) Food for Meals, Light Refreshments, and Beverages;
(3) Promotional Items [*includes, but is not limited to: clothing and commemorative items such as pens, mugs/cups, folders/folios, lanyards, and conference bags that are sometimes provided to visitors, employees, grantees, or conference attendees.*] ;
(4) Acquisition, by purchase or lease, of any interest in real property;
(5) Special rearrangement or alteration of facilities;
(6) Purchase or lease of **any** item of general purpose office furniture or office equipment regardless of dollar value. (General purpose equipment is defined as any items of personal property which are usable for purposes other than research, such as office equipment and furnishings, pocket calculators, etc.);
(7) Travel to attend general scientific meetings;
(8) Consultant Costs;
(9) Patient care costs;
(10) Accountable Government Property (defined as non-expendable personal property with an acquisition cost of $3,000 or more) and "sensitive items" (defined as items of personal property (supplies and equipment that are highly desirable and easily converted to personal use)), regardless of acquisition value;
(11) Printing Costs (as defined in the Government Printing and Binding Regulations; and
(12) Overtime (premium) compensation.

b. **Items requiring written Contracting Officer's Authorization prior to approval:**

1) Entering into certain types of subcontract of arrangements (See Article B.3.6 for specific obligations). Note that most consulting agreements require approval.

2) Domestic and Foreign Travel (see Subparagraph c.3);

4) Light Refreshment and Meal Expenditures - Requests to use contract funds to provide light refreshments and/or meals to either federal or nonfederal employees must be submitted to the Contracting Officer's Representative (COR), with a copy to the Contracting Officer, at least six (6) weeks in advance of the event and are subject to "HHS Policy on Promoting Efficient Spending: Use of Appropriate Funding for Conferences and Meetings, Food and Promotional Items and Printing and Publications." The request shall contain the following information: (a) name, date, and location of the event at which the light refreshments and/or meals will be provide; (b) a brief description of the purpose of the event; (c) a cost breakdown of the estimated light refreshments and/or meals costs; (d) the number of nonfederal and federal attendees receiving light refreshments and/or meals; and (e) if the event will be held at a government facility.

5) Clinical Study Protocols- a draft must be submitted for review and approval in advance of IRB submission.

6) Animal Study Protocols- a draft must be submitted for review and approval in advance of IACUC submission.

7) Testing for System Performance for Verification and Validation Protocols - a draft must be submitted for review and approval in advance of test occurring.

c. **Travel Costs**

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

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

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

Note: If travel is necessary, a COA will be required. Expenditures for travel (transportation, lodging, subsistence, and incidental expenses) incurred in direct performance of this contract shall not exceed the amount specified in each approved COA, without the prior written approval of the Contracting Officer.

In the event foreign travel is required, requests for foreign travel must be submitted at least four weeks in advance and shall contain the following:

(a) meeting(s) and place(s) to be visited, with costs and dates;
(b) name(s) and title(s) of Contractor personnel to travel and their functions in the contract project;
(c) contract purposes to be served by the travel;
(d) how travel of Contractor personnel will benefit and contribute to accomplishing the contract project, or will otherwise justify the expenditure of ASPR contract funds;
(e) how such advantages justify the costs for travel and absence from the project of more than one person if such are suggested; and
(f) what additional functions may be performed by the travelers to accomplish other purposes of the contract and thus further benefit the project.

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. STATEMENT OF WORK

a. Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government as needed to perform the **Statement of Work, dated May 28, 2014, set forth in SECTION J, Attachment Number 1, attached hereto and made a part of this contract.**

ARTICLE C.2. REPORTING REQUIREMENTS

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

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

All paper/hardcopy documents/reports submitted under this contract shall be printed or copied, double-sided, on at least 30 percent post-consumer fiber paper, whenever practicable, in accordance with FAR 4.302(b).

a. **Technical Reports**

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

1. **Monthly Progress Report**

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

The Contractor shall submit a Monthly Progress Report according to the dates set forth in ARTICLE F.2. of this contract. The format should include:

A cover page that includes the contract number and title; the type of report and period that it covers; the Contractor's name, address, telephone number, fax number, and e-mail address; and the date of submission; The progress report shall conform to the requirements set forth in the DELIVERABLES Article in SECTION F of this contract.

- SECTION I – An introduction covering the purpose and scope of the contract effort
- SECTION II - PROGRESS
- SECTION II Part A: OVERALL PROGRESS - A description of overall progress.
- SECTION II Part B: MANAGEMENT AND ADMINISTRATIVE UPDATE - A description of all meetings, conference calls, etc. that have taken place during the reporting period. Include progress on administration and management issues (e.g., evaluating, and managing subcontractor performance, and personnel changes). A standing organizational chart is to be included in this section.
- SECTION II Part C: TECHNICAL PROGRESS - For each activity related to Gantt chart, document the results of work completed and cost incurred during the period covered in relation to proposed progress, effort and budget. The report shall be in sufficient detail to explain comprehensively the

results achieved. The description shall include pertinent data and/or graphs in sufficient detail to explain any significant results achieved and preliminary conclusions resulting from analysis and scientific evaluation of data accumulated to date under the contract. The report shall include a description of problems encountered and proposed corrective action; differences between planned and actual progress, why the differences have occurred and what corrective actions are planned; preliminary conclusions resulting from analysis and scientific evaluation of data accumulated to date under the project.

- SECTION II Part D: PROPOSED WORK - A summary of work proposed related to Gantt chart for the next reporting period and preprints/reprints of papers and abstracts. Any revisions to the Timeline, Work Breakdown Structure (WBS) and Risk Assessment.
- SECTION III Part A: Earned Value Management Reporting: Contractor will provide a monthly Contract Performance Report (CPR) at an agreed upon reporting level (WBS level 2) using the BARDA provided WBS and a Variance Analysis Report. EVMS shall be applied to all Cost Plus Fixed Fee CLINs as part of the Integrated Master Project Plan following the Seven Principles of Earned Value Management. In accordance with FAR 52.215-2, Audit and Records-Negotiation, BARDA may request, on a quarterly or ad hoc basis that the Contractor provide raw data. BARDA may request additional data at a reporting level or at lower levels, as BARDA deems necessary..

A Monthly Progress Report will not be required in the same month that the Annual Technical Progress Report is submitted.

The first report shall be due the **15th Calendar day** after completion of the first full Calendar month and portion thereof of performance. Thereafter, reports shall be due on or before the 15th Calendar day following each reporting period.

2. **Annual Progress Report**

This report shall include a summation of the results of the entire contract work for the period covered. An Annual Technical Progress Report will not be required for the period when the Final Technical Progress Report is due. Monthly Progress Reports shall not be submitted in the same month when an Annual Progress Report is due.

The first Annual Progress Report shall be submitted in accordance with the date set forth in ARTICLE F.2. of this contract. Each Annual Progress Report shall include:

A Cover page that includes the contract number and title; the type of report and period that it covers; the Contractor's name, address, telephone number, fax number, and e-mail address; and the date of submission; The progress report shall conform to the requirements set forth in the DELIVERIES Article in SECTION F of this contract.

- SECTION I: EXECUTIVE SUMMARY - A brief overview of the work completed, and the major accomplishments achieved during the reporting period.
- SECTION II: PROGRESS
- SECTION II Part A: OVERALL PROGRESS - A description of overall progress.
- SECTION II Part B: MANAGEMENT AND ADMINISTRATIVE UPDATE - A description of all meetings, conference calls, etc. that have taken place during the reporting period. Include progress on administration and management issues (e.g. evaluating, and managing subcontractor performance; regulatory compliance audits, and personnel changes).
- SECTION II Part C: TECHNICAL PROGRESS - For each activity, document the results of work completed and cost incurred during the period covered in relation to proposed progress, effort and budget. The report shall be in sufficient detail to explain comprehensively the results achieved. The description shall include pertinent data and/or graphs in sufficient detail to explain any significant

results achieved and preliminary conclusions resulting from analysis and scientific evaluation of data accumulated to date under the contract. The report shall include a description of problems encountered and proposed corrective action; differences between planned and actual progress, why the differences have occurred and what corrective actions are planned; preliminary conclusions resulting from analysis and scientific evaluation of data accumulated to date under the project;

- SECTION II Part D: PROPOSED WORK - A summary of work proposed for the next year period to include an updated Gantt Chart.
- SECTION III Part A: Earned Value Management Reporting: Contractor will provide a quarterly Contract Performance Report (CPR) at an agreed upon (WBS level 3) reporting level using the BARDA provided WBS and a Variance Analysis Report. EVMS shall be applied to all Cost Plus Fixed Fee CLINs as part of the Integrated Master Project Plan following the Seven Principles of Earned Value Management. In accordance with FAR 52.215-2, Audit and Records-Negotiation, BARDA may request, on a quarterly or ad hoc basis that the Contractor provide raw data. BARDA may request additional data at a reporting level or at lower levels, as BARDA deems necessary.

Contractor also should include the following in the Annual Progress Report:

a. Copies of manuscripts (published and unpublished), abstracts, and any protocols or methods developed specifically under the contract during the reporting period; and

b. A summary of any Subject Inventions per the requirements under FAR Clause 52.227-11.

The first report shall cover the period September 15, 2014 **through** September 14, 2015 of this contract and shall be due within **30 Calendar days** after the Anniversary Date of the Contract.

3. **Draft Final Technical Progress Report and Final Technical Progress Report**

A Draft Final Report will be submitted to the Contracting Officer's Representative for review and comment at least 45 days prior to the contract completion date. Within 15 days of receipt, the Contracting Officer's Representative will provide the Contractor written comments on the Draft Final Report.

These reports are to include a summation of the work performed and results obtained for the entire contract period of performance. This report shall be in sufficient detail to describe comprehensively the results achieved. The Draft Final Report and Final Report shall be submitted in accordance with the DELIVERIES Article in SECTION F of the contract. An Annual Technical Progress Report will not be required for the period when the Final Technical Progress Report is due. The Draft Final Technical Progress Report and the Final Technical Progress Report shall be submitted in accordance with the dates set forth in ARTICLE F.2. of this contract. The report shall conform to the following format:

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

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

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

Draft Technical Progress Report: The Contractor is required to submit the Draft Final Technical Progress Report to the Contracting Officer's Representative and Contracting Officer. This report is due 45 Calendar days before the completion date of the contract. The Contracting Officer's Representative and Contracting Officer will review the Draft Final Technical Progress Report and provide the Contractor with comments within 15 Calendar days after receipt.

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

4. **Summary of Salient Results**

The Contractor shall submit, with the Final Report, a summary (not to exceed 400 words) of salient results achieved during the performance of the contract.

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

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

6. **FDA/Regulatory Agency Submissions**

7. **Other Reports/Deliverables**

a. **Study/Experiment/Test Plans** - The Contractor shall submit all study/experiment/test plans, designs, and protocols upon request by the COR.
b. **Meeting Minutes** - The Contractor shall provide an electronic copy of conference call meeting minutes/summaries to the Contracting Officer's Representative and Contracting Officer within five (5) business days after the conference call is held.
c. **Written request for modifications to the "developer's prototype"** - Detailed justification, sufficient for Certificate of Analysis, laying out the design changes required for the research instrument. Changes and requests to modify may come on two occasions.
d. **Audit Reports** – Report is required whenever an audit occurs.
e. **Reporting of Financial Conflict of Interest (FCOI)** - All reports and documentation required by 45 CFR Part 94, Responsible Prospective Contractors including, but not limited to, the New FCOI Report, Annual FCOI Report, Revised FCOI Report, and the Mitigation Report, shall be submitted to the Contracting Officer in Electronic format. Thereafter, reports shall be due in accordance with the

regulatory compliance requirements in 45 CFR Part 94. 45 CFR Part 94 is available at: http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=0af84ca649a74846f102aaf664da1623&rgn=div5&view=text&node=45:1.0.1.1.51&idno=45 . See Part 94.5, Management and reporting of financial conflicts of interest for complete information on reporting requirements.

ARTICLE C.3. SUBJECT INVENTION REPORTING REQUIREMENT

All reports and documentation required by FAR Clause 52.227-11 Patent Rights-Ownership by the Contractor, including, but not limited to, the invention disclosure report, the confirmatory license, and the Government support certification, one copy of an annual utilization report, and a copy of the final invention statement, shall be submitted to the Contracting Officer. A final invention statement (see FAR 27.303 (b)(2)(ii)) shall be submitted to the Contracting Officer on the expiration date of the contract. Reports and documentation submitted to the Contracting Officer shall be sent to the following email and/or address:

Pedro Godinez
Contracting Officer
DHHS/OS/ASPR/BARDA
330 Independence Avenue, S.W.
Room 644G
Washington, D.C. 20201

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

ARTICLE C.4. BI-MONTHLY CONFERENCE CALLS

Two conference calls between the Contracting Officer's Representative and the Contractor shall occur every month, or as directed by the Contracting Officer's Representative. During these calls the Principal Investigator will discuss the activities performed and deliverables achieved during the reporting period, any problems that have arisen and the activities planned for the ensuing reporting period. The first reporting period consists of the first half month of performance plus any fractional part of the initial month. Thereafter, the reporting period shall consist of each half Calendar month. Contractor may choose to include other key personnel on the conference call to give detailed updates on specific projects or this may be requested by the Contracting Officer's Representative.

ARTICLE C.5. PROJECT MEETINGS

The Contractor shall participate in Project Meetings to coordinate the performance of the contract, as requested by the Contracting Officer's Representative. These meetings may include face-to-face meetings with AMCG/BARDA in Washington, D.C. and at work sites of the Contractor. Such meetings may include, but are not limited to, meetings of the Contractor to discuss study designs, site visits to the Contractor's facilities, and meetings with the Contractor and HHS officials to discuss the technical, regulatory, and ethical aspects of the program. Subject to the data rights provisions in this contract, the Contractor must provide data, reports, and presentations to groups of outside experts and USG personnel as required by the Contracting Officer's Representative in order to facilitate review of contract activities.

ARTICLE C.6. IN-PROCESS-REVIEW

At its discretion, the Government may conduct an In-Process-Review (IPR) to evaluate whether to continue activities covered by the contract. Contractor shall provide a presentation detailing technical progress made towards completion of milestones following a prescribed template provided by the Government at an agreed upon date. The IPR will typically be conducted at DHHS facilities in Washington, DC. The contractor will be notified

by the Government of its intention to hold an IPR at least 30 calendar days prior to the scheduled IPR Presentation.

- Contractor shall provide final presentation 10 business days prior to each IPR Presentation.
- Contractor shall submit written justification of progress towards satisfying success criteria.
- If draft is provided prior to the final presentation submission, the Government will provide a written or verbal response, as appropriate.

ARTICLE C.7. SITE VISITS AND INSPECTIONS

At the discretion of the USG and independent of activities conducted by the Contractor, with ten (10) business days notice to the Contractor, the USG reserves the right to conduct site visits and inspections on an as needed basis.

SECTION D - PACKAGING, MARKING AND SHIPPING

Report Deliverables

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

Unless otherwise specified by the Contracting Officer, delivery of reports to be furnished to the Government under this contract (including invoices) shall be delivered to BARDA both in Hard Copy, and Electronically along with a concurrent email notification to the Contracting Officer and COR (as defined in SECTION G, CONTRACT ADMINISTRATION) summarizing delivery as follows:

Mailing Address
Bonnie Shen
Contracting Officer's Representative
DHHS/OS/ASPR/BARDA
330 Independence Avenue, S.W.
Room G644
Washington, D.C. 20201

E-Mail Address
[redacted]@hhs.gov

Mailing Address
Pedro Godinez
Contracting Officer
DHHS/OS/APSR/AMCG
330 Independence Avenue, S.W
Room G644
Washington, D.C. 20201

E-Mail Address
[redacted]@hhs.gov

Prototype Deliverables:

The Contractor will ship the prototypes to the COR at the address indicated above using available courier services and shipping insurance. The Contractor will package the prototypes for shipment in appropriate containers and with enough packing material to protect the units from damage during shipment.

Option Items Deliverables

Upon notification by the Contractor that Ventilators are ready for Delivery, the Government will provide specific instructions.

SECTION E - INSPECTION AND ACCEPTANCE

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

b. For the purpose of this SECTION, the designated Contracting Officer's Representative (COR) is the authorized representative of the Contracting Officer.

c. For report deliverables, inspection and acceptance will be performed at:

Office of Acquisition Management, Contracts, and Grants (AMCG)
Office of the Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services
330 Independence Avenue, S.W., Room G644
Washington, D.C. 20201

d. For option items, inspection and acceptance will be performed at the specified delivery site.

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

FAR Clause **52.246-2, Inspection of Supplies - Fixed Price** (August 1996).
FAR Clause **52.246-3, Inspection of Supplies - Cost-Reimbursement** (May 2001).
FAR Clause **52.246-4, Inspection of Services - Fixed Price** (August 1996).
FAR Clause **52.246-5, Inspection of Services - Cost-Reimbursement** (April 1984).
FAR Clause **52.246-9, Inspection of Research and Development (Short Form)** (April 1984).
FAR Clause **52.246-16, Responsibility for Supplies** (April 1984).

SECTION F - DELIVERIES OR PERFORMANCE

ARTICLE F.1. PERIOD OF PERFORMANCE

a. The period of performance of this contract shall be from **September 15, 2014 through September 14, 2017.**

b. If the Option is exercised, the contract expiration date will be extended in accordance with the deliverable schedule in Article F.2.; **21 months from the time the Option is exercised.**

ARTICLE F.2. DELIVERABLES

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

a. The items specified below as described in the REPORTING REQUIREMENTS Article in SECTION C of this contract will be required to be delivered F.O.B. Destination as set forth in FAR 52.247-35, F.O.B. DESTINATION, WITHIN CONSIGNEES PREMISES (APRIL 1984), and in accordance with and by the dates specified below:

Phase	WBS Section	Due (from CA)	Deliverable	Description
PHASE III: Requirements & Planning	3.1	2mo	Product Requirements Document	Specific product functional, environmental, safety, and regulatory requirements.
	3.1	2mo	Quality Information	Historical quality information of related products, including CAPAs, MDRs, complaints, etc. Design Quality Engineering will work with Quality Systems to obtain the appropriate information.
	3.2.1	2mo	Project Plan	Provides design and development plans, and captures strategies of functional groups.
	3.2.2	3mo	Risk Assessment - Initial Hazard Analysis	Identifies potential harms, hazards, and risks which are classified by severity.
	2.2	3mo	Requirements and Planning Review Minutes	Review held at the end of the Requirements and Planning phase.
PHASE IV: System Design	4.1.1	4mo	System Architecture Document	Specifies the major components in the product and the external interfaces to other products, accessories, and/or users in their environments.
	4.3.2	8mo	Hardware Requirements Document	Specifies electrical and mechanical sub- system requirements, including test and acceptance criteria where necessary.
	4.1.2	8mo	User Interface Document	Describes the user interface with the device controls and displays.
PHASE IV: System Design	4.3.3	9mo	Software Requirement Specification	Provides requirements associated with ventilator software, including details for test planning.
	4.3.4	10mo	Mass Casualty Patient Monitoring SW Requirements Specification	Provides requirements associated with Mass Casualty Patient Monitoring (MCPM) software, including details for test planning.

Phase	WBS Section	Due (from CA)	Deliverable	Description
PHASE IV: System Design	4.3.5	10mo	System - Subsystem Design Trace Matrix	Provides traceability as required from the PRD to the sub-system specifications. PRD- SRS trace matrix specified in QSP 7.3-277.
	4.3.1	8mo	System FMEA/Sub-system Design Analysis	Describes system architecture analysis of failure modes, effects, criticality, using FMEA or applicable procedures to determine important components and characteristics.
	4.3.5	10mo	Standards Requirements	Provides the detailed requirements that need to be considered as part of the product's requirements.
	4.3.1	8mo	Risk Assessment: Detailed Hazard Analysis	Review and update the Risk Assessment from the previous phase to incorporate additional risks and control measures defined during system design activities.
	4.4	6mo	Software Development Plan	Describes how engineering will develop software, including iteration plans, configuration management, and software quality assurance.
	4.4	6mo	Design Verification and Validation Plan	Describes the approach and specific testing that will be conducted for appropriate V&V and compliance testing. Will Identify 3rd party test approach and gain BARDA approval
	4.4	6mo	Reliability Plan	Sets out the reliability assurance activities that will be undertaken in conjunction with the development team to assure that that the design meets or exceeds its specified reliability goals.
	4.4	6mo	Risk Management Plan	Defines the specific project activities that will capture and assess safety risks, define and verify control measures.
	4.4	6mo	Regulatory Plan	Presents the approach that will be taken to obtain any necessary regulatory approvals.
	4.4	6mo	Labeling Plan	Presents the approach to assure proper labeling and language translations for the anticipated market.
	4.4	6mo	Industrial Design Plan	Describes any research or involvement of the Industrial Design group.
	4.4	6mo	Clinical Plan	Presents the general approach that will be used in the clinical analysis of the product.
	4.4	6mo	Global Sourcing Plan	Plans for new suppliers, new 7.9, and/or new technologies.
	4.4	6mo	Manufacturing Plan	Defines the plans for manufacturing to include activities for developing the facilities, processes, and equipment for production.
	4.4	6mo	Service Plan	Plan to handle technical service for the products, including field repairs, spare parts, and service manuals. Includes development of training for service technicians. May also include product support.
	4.4	6mo	Customer Support and User Training Plan	Provides initial plans for product launch to establish special requirements related to training materials for clinician and inexperienced care providers with limited or no respiratory training.
	4.4	6mo	Human Factors Plan	The Human Factors plan presents the planned human factors engineering (HFE) activities the project. Planned activities are designed to ensure that the product is safe and effective for its intended use and ensure the usability of the product

Phase	WBS Section	Due (from CA)	Deliverable	Description
	2.2.1	10mo	Initial Product Cost Targets and Architecture Allocation	Captures initial product cost targets and allocates cost budget across major architectural components.
	2.2.1	10mo	System Design Review Minutes	Reviews the results of all the activities and issues associated with System Design to assure that the project is prepared to proceed into detailed design.
PHASE V: Detailed Design	5.5.2	16mo	Bill Of Materials	The BOM identifies all other parts, components, assemblies that should be specified and items included in the MDL below.
	5.3.1	22mo	Component Specifications	Provides the specifications of purchased components, including dimensional, functional requirements, shelf life, packaging, and labeling requirements.
PHASE V: Detailed Design	5.5.1	19mo	Assembly Manufacturing Drawings/Design, Assembly Drawings	Captures the specifications of manufactured items and subassemblies (purchased assemblies).
PHASE V: Detailed Design	4.2	4mo	EB1 Engineering Build Report	Provides record of the configuration of engineering or pre-production devices, including design, process, supply, and people considerations.
	5.1.3	10mo	EB2 Engineering Build Report	
	5.2.3	16mo	EB3 Engineering Build Report	
	5.3.4	23mo	EB4 Engineering Build Report	
	5.3.2	22mo	Software Design Descriptions	Describes the detailed design of the ventilator software including the definition of modules and their interfaces.
	5.3.3	20mo	Mass Casualty Patient Monitoring Design Description	Describes the detailed design of the Mass Casualty Patient Monitoring software including the definition of modules and their interfaces.
	5.3.2	22mo	Software Build Procedure	Documents the identification of source code modules, source location, development environment, and build procedure so that the ventilator executable code is reproducible.
	5.3.3	20mo	MCPM Software Build Procedure	Documents the identification of source code modules, source location, development environment, and build procedure so that the MCPM executable code is reproducible.
	5.3.2	22mo	Software Release Notes	Documents the status of an iteration of ventilator software used to record the design history record for software components.
	5.3.3	20mo	MCPM Software Release Notes	Documents the status of an iteration of MCPM software used to record the design history record for software components.
	5.3.3	20mo	Code Review Meeting Minutes/Formal Technical Design Review Records	Documents the results of reviews, including a summary of what reviews were conducted (files, reviewers, issues). Includes code review meeting minutes
	4.2	8mo	EB1 Technical Design Review Records	
	5.1.1	10mo	EB2 Technical Design Review Records	Initial Hardware Design

Phase	WBS Section	Due (from CA)	Deliverable	Description
	5.1.2	10mo	EB2 Technical Design Review Records	Initial Software Design
	5.2.1	15mo	EB3 Technical Design Review Records	Hardware Design
	5.2.2	14mo	EB3 Technical Design Review Records	Software Design
PHASE V: Detailed Design	5.3.1 & 5.3.2	22mo	EB4 Technical Design Review Records	
	5.3.3	20mo	MCPM Code Review Meeting Minutes	
	5.3.1	22mo	Hardware Design Descriptions	Describes the detailed design of the ventilator hardware including the definition of components, sub-assemblies and their interfaces.
	5.1.1	10mo	Detailed Design Analysis (DFMEA for each sub- component identified)	Documents the analysis of the detailed designs, components, etc. May include multiple deliverables to cover electrical and mechanical analyses such as dFMEAs.
	5.6.2	23mo	Generation of Catalogue Profile and Customer Complaint Codes	After the development of the Detailed Design Analysis, Design Quality Engineering will work with Quality Management Systems to facilitate the generation of the Catalogue Profile and a draft of the associated Customer Complaint Codes.
	5.6.2	23mo	Risk Assessment - Detailed Hazards Analysis and Mitigation Control Measures	Captures all risk controls identified in detailed design phase. Includes the following: Risk Matrix; Key Components List; Usability File; Product Security Risk Assessment; and Privacy Impact Assessment.
	5.5.2	16mo	Key Component/ Process Characteristics	For each component, subassembly, or finished good, this deliverable(s) identifies the type of supplied material, supplier information, key components and process characteristics of the material.
	4.2	4mo	EB1 Engineering Test Procedures	Outlines the testing that is conducted by engineering to assure the design for components, subsystems, and the product complies with the design specifications.
	5.1.4	12mo	EB2 Engineering Test Procedures	
	5.2.4	18mo	EB3 Engineering Test Procedures	
	5.3.5	25mo	EB4 Engineering Test Procedures	
PHASE V: Detailed Design	4.2	4mo	EB1 Engineering Test Reports	Documents the results of the engineering testing to qualify components and the overall design.
	5.1.4	12mo	EB 2 Engineering Test Reports	
	5.2.4	18mo	EB 3 Engineering Test Reports	
	5.3.5	25mo	EB 4 Engineering Test Reports	

Phase	WBS Section	Due (from CA)	Deliverable	Description
PHASE V: Detailed Design	5.6.3	25mo	Design V&V Test Procedures	Documents the test procedures that will be used to verify product requirements. Add rows as necessary.
	5.6.3	25mo	Design V&V Trace Matrix	Provides trace matrix between requirements and V&V activities, test procedures, reports. Add rows as necessary.
	5.6.3	25mo	Reliability Assurance Deliverables	Records of reliability activities done in accordance with reliability plan, including initial results that provide inputs to design.
	5.5.1	19mo	Device History Record Specified	Provides the format and content of the DHR to be used in production of devices.
	5.5.1	19mo	Process Analysis (Process FMEA)	Identifies and assess potential manufacturing process risks as input to process validation plan and manufacturing quality plan. Detection methods are identified as part of the manufacturing procedures and instructions.
	5.5.1	19mo	Process Master Validation Plan (MVP)	Documents the process flow and the test requirements to validate the manufacturing equipment, process and instructions. It also includes the aspects related to the servicing process, equipment and instructions
	5.5.1	19mo	High Volume Surge Capable Mfg. Plan	Document includes plans to prepare facilities, tooling, and capabilities to meet the surge capacity demand of 1,700 units per month and deliver 10,000 units in 6-months.
	5.5.1	19mo	Final Test Procedures	Documentation associated with on-line testing of the device.
	5.5.1	19mo	Equipment Requirements Specification	Documents specifications for new or modified equipment intended to be used for manufacturing, testing, or servicing a product.
	5.5.1	19mo	Equipment Calibration Procedures	Documents necessary calibration activities that are required for the manufacturing and test equipment.
	5.5.1	19mo	Equipment Functional Specification	Detailed documentation of the equipment, including maintenance procedures and validation
	5.5.1	19mo	Return to Stock Procedure	Assures proper traceability and service history.
	5.5.1	19mo	Operation Specification / Method Sheets	Methods and procedures documentation associated with manufacturing processes.
	5.5.2	16mo	Material Qualification Agreement	The Material Qualification Agreement (MQA) is a signatory agreement which clearly identifies qualification criteria for supplied material
	5.4.3	16mo	Lay Caregiver & Clinical Training Materials (Marketing Literature)	Captures literature that complies with all applicable requirements with regard to legibility, accuracy, product claims, educational materials, and user understanding.
	5.4	16mo	Manual / Instructions for Use (Labeling)	Review and approve device and packaging labels, artwork, and drawings, manuals, inserts, etc.
	5.5.3	19mo	Service and SNS Maintenance Manual & Plan	Provides the technical information for how to service and repair the device.
PHASE V: Detailed Design	5.4	16mo	Labeling List	List of final, released product labeling

Phase	WBS Section	Due (from CA)	Deliverable	Description
	5.5.1	19mo	Device Traceability	Documents the level of device traceability that is required and how it will be carried out. Engineering establishes the requirements with Design QE, Regulatory, Risk Assessment, Supplier Quality input. Engineering Services enters data as needed to support SAP tracking.
	5.5.1	19mo	Component Traceability and Lot Tracking	Documents the level of component traceability that is required and how it will be carried out. Engineering establishes the requirements with Design QE, Regulatory, Risk Assessment, Supplier Quality input. Engineering Services enters data as needed to support SAP tracking.
	5.5.1	19mo	Design Transfer Plan	The Design Transfer Plan is used to establish and track the activities to complete design transfer into production.
	2.2	25mo	Product Cost Estimates	Captures estimated component and assembly costs based on design documentation produced in the detailed design phase.
	2.2	25mo	Detailed Design Review Minutes	Reviews items associated with Detailed Design phase.
PHASE VI: Verification	6.1	28mo	PP1 Engineering Build Report	Provides record of materials used, procedures, personnel involved, dates, and traceability information for engineering pre-production devices. Include production equivalency analysis?
	6.1	28mo	Fully Functional fully-kitted prototype	Physical fully functional fully-kitted ventilator prototype. Device is intended to have full functionality but official verification has not been complete.
	6.2	32mo	PP1 Design Verification Report	Provides a record of all verification testing, including configurations tested, as-run procedures, results, and conclusions. Add rows as necessary to identify the deliverables/reports. Testing completed by agreed USG upon independent third party testing facility
	6.2	32mo	PP1 Validation and Human Factors Test Report	Presents the results of Validation and Human factors testing as captured in the V&V and Human Factors plan.
	6.2	32mo	PP1 EMC Compliance Test Report	Presents the results of any EMC testing that is required per regulatory and safety standards.
	6.2	32mo	PP1 Shock & Vibration Compliance Test Report	Presents the results of any shock and vibration testing that is required per regulatory and safety standards.
	6.2	32mo	PP1 Standards Compliance Test Report	Documents the results of safety testing that is required per regulatory and safety standards.
	6.2	32mo	PP1 Biocompatibility Assessment & Report	Assessment is performed of all materials that come into contact with the manufacturer, service provider or the user.
	6.2	32mo	PP1 Packaging Test Report	Documents the results of ISTA shipping container testing performed for the device.
PHASE VI: Verification	6.2	33mo	PP1 Reliability Report	Documents the results of reliability activities to verify the reliability of the product design.
PHASE VI: Verification	6.7.2	36mo	Risk Assessment Hazards Analysis and Verification	Risk Matrix; Update Key Components List; Update Usability File; Product Security Risk Assessment; Privacy Impact Assessment

Phase	WBS Section	Due (from CA)	Deliverable	Description
	2.2	35mo	Updated Cost Estimates	Captures updated estimated component and assembly costs based on design documentation updates produced in the verification design phase.
	2.2	35mo	Verification Review Meeting Minutes	Reviews items associated with Design Verification phase.
PHASE VI: Validation & Design Transfer	6.6.2	36mo	Process Validation Records	Protocols and reports that validate the manufacturing equipment, procedures and process (IQ, OQ, and PQ)
	6.6.2	36mo	Pilot Run History Form	Documents the completion of tasks necessary to commence a pilot production build.
	6.6.2	36mo	Design Validation Report	Documents the results of validation activities. Add rows as necessary to identify the deliverables/reports.
	6.7.1	36mo	Clinical Report	Presents the results or reports from clinical studies, which were identified in the clinical plan.
	6.7.2	35mo	Final Risk Assessment	Risk Matrix; Update Key Components List; Update Usability File; Product Security Risk Assessment; Privacy Impact Assessment
	2.2	36mo	Validation Review Meeting Minutes	Review meeting minutes held at the end of Design Validation phase.
	6.3	33mo	Final Fully Kitted Ventilator Technical Specifications	Documents that captures full published technical and performance specifications of the ventilator system. Sub-set of product requirements document. Typically captured as part of the operators manual.
	2.2	36mo	List of Known/ Deferred Defects	Documents the known defects that are deferred and the rationale for releasing product with these defects.
	6.6.1	27mo	Material Qualification Agreement	Final signatures entered on the MQA towards qualification assurance on the supplied material
	6.6.2	36mo	Process Master Validation Report	MVP report to include status of all process validation activities.
	6.7.1	36mo	Essential Requirements Technical File Index	Index of the documents that comprise the MDD & RTTE technical files.
PHASE VI: Validation & Design Transfer	6.7.1	36mo	Design History File Index	Index of all design history file documents.
	6.7.1	36mo	Regulatory Assessment & Checklist	Completion of checklist to show requirements for regulatory review.
	6.6.2	36mo	Design Transfer Plan Report	Design Transfer Plan report with status to show activities complete.
PHASE VI: Validation & Design Transfer	2.2	36mo	Product Detailed Quotation	Final production quotation to purchase fully kitted ventilator system.
	2.2	36mo	Final Design Review Meeting Minutes	Document meeting minutes of Final Design Review held at the end of the Design Transfer phase.
	2.2	36mo	Final Report	Final program report to BARDA. Summary of all relevant project deliverables, actual project budget, and actual project schedule.

b. The items specified below will be required to be delivered F.o.b. Destination as set forth in FAR 52.247-35, F.o.b. DESTINATION, WITHIN CONSIGNEES PREMISES (APRIL 1984), and in accordance with and by the dates specified below:

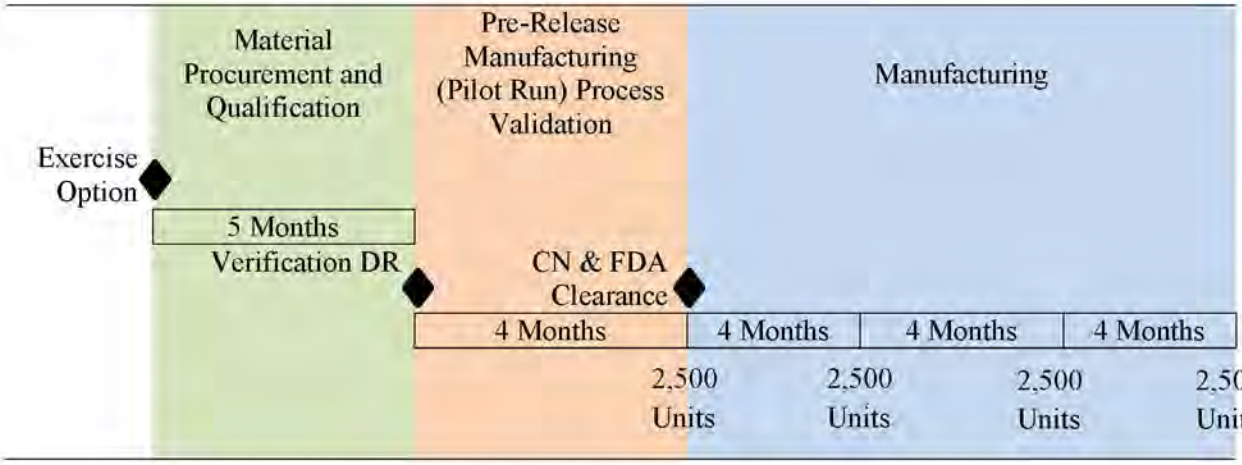
WBS Section	Due	Deliverable	Description
5.1.4	12 mo	One Ventilator Prototype	EB2 Prototype Unit
6.2	32 mo	One Ventilator Prototype	PP1 Production Prototype Unit
2.1.6	36 mo	One Ventilator Prototype	Released Patient Ready Prototype Unit Fully Kitted Final Configuration

Option	Description of Option Item	Quantity (Units)
Option One	New Model Initial Production Fully Kitted FDA-Approved AAHSV Ventilator plus Rugged Basic Pulse Oximeter and Colorimetric Co2 Intubation Monitor	10,000

Upon notification by the Contractor that Ventilators are ready for Delivery, the Government will provide specific instructions.

c. The above items shall be addressed and delivered in accordance to SECTION D.

d. Estimated lead times for Option One are as follows:



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

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

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:

52.242-15, Stop Work Order (AUGUST 1989) with ALTERNATE I (APRIL 1984).
52.247-35, F.O.B. Destination Within Consignees Premises (APRIL 1984).

SECTION G - CONTRACT ADMINISTRATION DATA

ARTICLE G.1. CONTRACTING OFFICER

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

Pedro Godinez, Contracting Officer
DHHS/OS/ASPR/AMCG
330 Independence Avenue, S.W.
Room G644
Washington, D.C. 20201
E-mail: [redacted]@hhs.gov

1) The Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds. No person other than the Contracting Officer can make any changes to the terms, conditions, general provisions, or other stipulations of this contract.
2) The Contracting Officer is the only person with the 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 reimburse to the Contractor of any costs incurred during the performance of this contract; (5) otherwise change any terms and conditions of this contract.
3) No information, which may be received from any person employed by the US Government, or otherwise, shall be considered grounds for deviation from any stipulation of this contract, unless it is information which may be contained in an authorized modification to this contract, duly issued by the Contracting Officer.
4) The Government may unilaterally change its CO designation.

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

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

Bonnie Shen
Contracting Officer's Representative (COR)
Biomedical Advanced Research and Development Authority (BARDA)
Office of the Assistant Secretary for Preparedness and Response
Department of Health and Human Services

The COR is responsible for:

1) Monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements;
2) Assisting the Contracting Officer in interpreting the statement of work and any other technical performance requirements;
3) Performing technical evaluation as required;
4) Performing technical inspections and acceptances required by this contract; and
5) Assisting in the resolution of technical problems encountered during performance.

The COR will assist in resolving technical issues that arise during performance. The COR however is not authorized to change any contract terms or authorize any changes in the Statement of Work or modify or extend the period of performance, or authorize reimbursement of any costs incurred during performance. The Contractor is advised to review Federal Acquisition Regulation ("FAR") Clause 52.243-2 (Changes-Cost reimbursement contracts Alternative V), which is incorporated by reference into this contract. (See ARTICLE I.1.)

The Contracting Officer is the only person with authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the statement of work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor for any costs incurred during the performance of this contract; or (5) otherwise change any terms and conditions of this contract. The Government may unilaterally change its COR designation.

ARTICLE G.3. CONTRACT FINANCIAL REPORT

1) Financial reports on the attached Financial Report of Individual Project/Contract (see Attachments 2 and 3) shall be submitted by the Contractor in accordance with the instructions for completing this form, which accompany the form, in hard copy and an electronic copy, not later than the 15th business day after the close of the reporting period. The line entries for subdivisions of work and elements of cost (expenditure categories) which shall be reported within the total contract are discussed in paragraph 5., below. Subsequent changes and/or additions in the line entries shall be made in writing.

2) Unless otherwise stated in that part of the instructions for completing this form, entitled "PREPARATION INSTRUCTIONS," (see Attachment 4) all columns A through J, shall be completed for each report submitted.

3) The first financial report shall cover the period consisting of the first full calendar month following the date of the contract, in addition to any fractional part of the initial month. Thereafter, reports will be on a **Monthly** basis. If the contractor fails to submit timely financial reports and invoices or is delinquent on submission of financial reports by an excess of 90 Calendar days, a "Stop Work Order" may be issued by the Government, until the delay is resolved.

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

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

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

1) The billing address that should be shown on the invoice is the same as defined in ARTICLE G.1. of this contract.

2) The Contractor shall submit two paper copies to the address provided in ARTICLE G.1. of this contract, as well as a hard copy and an electronic copy of contract **Monthly invoices/financial reports** to the Contracting Officer as defined above, in ARTICLE G.4. of this contract.

3) Contractor invoices/financial reports shall conform to the form, format, and content requirements of the instructions for Invoice/Financing requests and Contract Financial Reporting made a part of the contract in Section J (See also ARTICLE B. and Attachment 2) .

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

5) The Contractor agrees to immediately notify the Contracting Officer in writing if there is an anticipated overrun (any amount) or unexpended balance (greater than 10 percent) of the estimated costs for the base segment or

any option segment(s) (See estimated costs under Articles B.2. and B.3., of the contract) and the reasons for the variance. Also refer to the requirements of the Limitation of Cost FAR 52.232-20 clause in the contract.

6) All invoice submissions shall be in accordance with FAR Clause 52.232-25 (c) in Section I of this contract.

7) The Contractor shall reference any applicable Contractor Officer Authority (COA) numbers when requesting reimbursement on the invoice.

ARTICLE G.5. REIMBURSEMENT OF COST

1) The Government shall reimburse the Contractor the cost determined by the Contracting Officer to be allowable (hereinafter referred to as allowable cost) in accordance with the clause entitled Allowable Cost and Payment in Section I, Contract Clauses, and FAR Subpart 31.7. Examples of allowable costs include, but are not limited to, the following:

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

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

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

   d) Travel costs including per diem or actual subsistence for personnel while in an actual travel status in direct performance of the work and services required under this contract subject to the following and the restrictions in Article B.4(c):

      (i) Air travel shall be by the most direct route using "air coach" or "air tourist" (less than first class) unless it is clearly unreasonable or impractical (e.g., not available for reasons other than avoidable delay in making reservations, would require circuitous routing or entail additional expense offsetting the savings on fare, or would not make necessary connections).

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

      (iii) Costs incurred for lodging, meals, and incidental expenses shall be considered reasonable and allowable to the extent that they comply with FAR 31.7.

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

   e) For further provisions on funding, see the LIMITATION OF COSTS clause referenced in Part II, Contract Clauses.

ARTICLE G.6. GOVERNMENT PROPERTY

a. In addition to the requirements of the clause, GOVERNMENT PROPERTY, incorporated in SECTION I of this contract, the Contractor shall comply with the provisions of HHS Publication, "HHS Contracting Guide for Contract of Government Property," which is incorporated into this contract by reference. This document can be accessed at: http://oamp.od.nih.gov/sites/default/files/appendix_q_hhs_contracting_guide.pdf

Among other issues, this publication provides a summary of the Contractor's responsibilities regarding purchasing authorizations and inventory and reporting requirements under the contract.

Requests for information regarding property under this contract should be directed to the Contracting Officer.

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

ARTICLE G.7. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

a. Contractor Performance Evaluations

Interim and final evaluations of Contractor performance will be prepared on this contract in accordance with FAR Subpart 42.15. The final performance evaluation will be prepared at the time of completion of work. In addition to the final evaluation, interim evaluation will be prepared After completion of one year of performance.

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

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

b. Electronic Access to Contractor Performance Evaluations

Contractors may access evaluations through a secure Web site for review and comment at the following address: http://www.cpars.gov.

ARTICLE G.8. PROVIDING ACCELERATED PAYMENT TO SMALL BUSINESS SUBCONTRACTORS, FAR 52.232-40 (December 2013)

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

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

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

ARTICLE G.9. INDIRECT COST RATES

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

DHHS/OS/ASPR/AMCG
330 Independence Avenue, S.W.
Room G644
Washington, D.C. 20201

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

(End of Clause)

ARTICLE G.10. ESTABLISHMENT OF INDIRECT COST RATE

The Contractor may bill indirect costs at temporary billing rates of Fringe Benefit & Overhead Rate of 58.00% (of Total Direct salaries excluding paid absences(vacation, holiday, and sick)) as agreed on the April 11, 2014 Bilateral Provisional Indirect Cost Rate Agreement between Philips and DHHS/ASPR; until such time as indirect costs have been established, provided, that the Contractor's indirect cost proposal is submitted to the cognizant office responsible for negotiating indirect costs no later than September 14, 2015. If, the indirect cost proposal is not submitted in a timely manner, any temporary indirect costs billed after this due date will be suspended until such time as the indirect cost proposal is submitted.

ARTICLE G11. OVERTIME COMPENSATION

No overtime (premium) compensation is authorized under the subject contract. Billing of actual hours should be limited to total productive hours in a month.

SECTION H - SPECIAL CONTRACT REQUIREMENTS

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

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

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

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

ARTICLE H.2. HUMAN SUBJECTS

Research projects involving humans and/or human specimens can only be initiated with written approval by the Contracting Officer's Representative.

The Good Clinical Practice Regulations (GCP)(21 CFR Parts 50, 54, 56 312)(45 CFR Part 46)(ICH E6) as well as other applicable Federal and state regulations will be standards that apply for use of human subject and/or human specimens in clinical studies.

If at any time during the life of the contract, the Contractor fails to comply with GCP as identified by regulations outline above , the Contractor shall have thirty (30) Calendar days from the time such material failure is identified to cure such or initiate cure to the satisfaction of the Government Contracting Officer's Representative. If the Contractor fails to take such an action within the thirty (30) Calendar day period, then the contract may be terminated.

ARTICLE H.3. MANUFACTURING STANDARDS

The regulations pertaining to diagnostic products (21 CFR Part 820, Quality System Regulation) will be the standard to be applied for manufacturing, processing, packaging, storage and delivery of this product.

If at any time during the life of the contract, the Contractor fails to comply with GMP in the manufacturing, processing, packaging, storage, stability and other testing of the manufactured drug substance or product and delivery of this product and such failure results in a material adverse effect on the safety, purity or potency of the product (a material failure) as identified by the FDA, the Contractor shall have thirty (30) Calendar days from the time such material failure is identified to cure such material failure. If the Contractor fails to take such an action to the satisfaction of the Contracting Officer's Representative within the thirty (30) Calendar day period, then the contract may be terminated.

ARTICLE H.4. NEEDLE DISTRIBUTION

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

ARTICLE H.5. ACKNOWLEDGEMENT OF FEDERAL FUNDING

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

ARTICLE H.6. CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH

The Contractor shall not use contract funds for (1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.204(b) and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)). The term "human embryo or embryos" includes any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

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

ARTICLE H.7. DISSEMINATION OF FALSE OR DELIBERATELY MISLEADING INFORMATION

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

ARTICLE H.8. PRIVACY ACT APPLICABILITY

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

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

3) The Contractor shall follow the Privacy Act guidance as contained in the Privacy Act System of Records number 09-25-0200. This document may be obtained at the following link:

http://oma.od.nih.gov/ms/privacy/pa-files/0200.htm

ARTICLE H.9. OMB CLEARANCE

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

ARTICLE H.10. SUBCONTRACTING PROVISIONS

a. **Small Business Subcontracting Plan**

1. The Small Business Subcontracting Plan, dated March 31, 2014 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, 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**

The Contractor shall submit the following Subcontracting reports electronically via the "electronic Subcontracting Reporting System (eSRS) at http://www.esrs.gov .

1. Individual Subcontract Reports (ISR)

   Regardless of the effective date of this contract, the Report shall be due on the following dates for the entire life of this contract:
   April 30th
   October 30th
   Expiration Date of Contract

2. Summary Subcontract Report (SSR)
   Regardless of the effective date of this contract, the Summary Subcontract Report shall be submitted annually on the following date for the entire life of this contract.
   October 30th

For both the Individual and Summary Subcontract Reports, the Contracting Officer shall be included as a contact for notification purposes at the following e-mail address: [redacted]@hhs.gov

ARTICLE H.11. FULL EARNED VALUE MANAGEMENT SYSTEM, HHSAR 352.234-3 (October 2008)

a. The Contractor shall use an Earned Value Management System (EVMS) that has been validated and accepted by the Cognizant Federal Agency (CFA) as being 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 validated and accepted by the CFA at the time of award, see paragraph (b) of this clause. The Contractor shall submit EVM reports in accordance with the requirements of this contract.

b. If, at the time of award, the Contractor's EVM system has not been validated and accepted by the CFA as complying with EVMS 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 and timely actions to meet the milestones in the Contractor's EVMS plan approved by the Contracting Officer.

c. HHS requires the Contractor to obtain validation and acceptance of its EVM system by the CFA during the base period of performance of this contract. The Contracting Officer or designee will conduct a Compliance Review to assess the Contractor's compliance with its approved plan. If the Contractor does not follow the approved implementation schedule or correct all resulting system deficiencies noted during the Compliance Review within a reasonable time, the Contracting Officer may take remedial action, which may include, but is not limited to, suspension of or reduction in progress payments, or a reduction in fee.

d. HHS will conduct an Integrated Baseline Review (IBR). If a pre-award IBR has not been conducted, a post-award IBR will be conducted by HHS as early as practicable, but no later than ninety (90) days after contract award. The Contracting Officer may also require an IBR as part of the exercise of an option or the incorporation of a major modification.

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 30 calendar days 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 14 calendar days 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 requirements referenced in paragraph (a) of this clause.

g. The Contractor shall require the subcontractors specified below to comply with the requirements of the clause: (Insert list of applicable subcontractors.)

(End of clause)

ARTICLE H.12. CONFLICT OF INTEREST

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

H.13. ADDITIONAL BACKGROUND PATENT REQUIREMENTS

In addition to the Government license rights in FAR 52.227-11, the contractor grants for and on behalf of the US Government a fully paid up, royalty free, non-exclusive, irrevocable, non-transferable, world-wide license to rights that it owns or controls in inventions or patents that cover the subject ventilator or accessories for the purpose of placing the subject ventilator in a Government stockpile. This license is limited to: the use, manufacture, support, repair, sustainment, and distribution for the stockpiling of subject ventilators and accessories exclusively for Government's purpose using the contractor's specifications.

The Contractor shall promptly notify the Government in writing upon the award of any subcontract containing Patent Rights identifying the Subcontractor, and the work to be performed under the subcontract. Upon the request of the Government the Contractor shall furnish a copy of the subcontract. In the event that the contractor awards a subcontract covering the subject invention, the mutual obligations of the contractor to the US Government shall become the mutual contractual obligations between the subcontractor and the US Government. The contractor shall ensure that the rights granted the US Government under FAR Clause 52.227-11 and FAR Subpart 27.3 are incorporated into any subcontract, covering any subject invention, regardless of the tier , pursuant to FAR clause 52.227-11(k)(3).

ARTICLE H.14. PUBLICATION AND PUBLICITY

No information related to data obtained under this contract shall be released or publicized without the prior written consent of BARDA.

In addition to the requirements set forth in HHSAR Clause **352.227-70, Publications and Publicity** incorporated by reference in SECTION I of this contract, Section 507 of P.L. 104-208 mandates that Contractors funded with Federal dollars, in whole or in part, acknowledge Federal funding when issuing statements, press releases, requests for proposals, bid solicitations and other documents. Contractors are required to state: (1) the percentage and dollar amounts of the total program or project costs financed with Federal money and; (2) the percentage and dollar amount of the total costs financed by nongovernmental sources.

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

> "This project has been funded in whole or in part with Federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, under Contract No. HHSO100201400005C"

ARTICLE H.15. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

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

US Department of Health and Human Services
Office of Inspector General

ATTN: OIG HOTLINE OPERATIONS
P.O. Box 23489
Washington, D.C. 20026

ARTICLE H.16. PROHIBITION ON CONTRACTOR INVOLVEMENT WITH TERRORIST ACTIVITIES

The Contractor acknowledges that U.S. Executive Orders and Laws, including but not limited to E.O. 13224 and P.L. 107-56, prohibit transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. It is the legal responsibility of the Contractor to ensure compliance with these Executive Orders and Laws. This clause must be included in all subcontracts issued under this contract.

ARTICLE H.17. USE OF FUNDS FOR PROMOTIONAL ITEMS

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

ARTICLE H.18. 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.

ARTICLE H.19. SECURITY PLAN REQUIREMENTS

The Contractor is required to have an established security plan for the manufacturing, storage and distribution work performed under this contract that ensures against theft, tampering or destruction of pertinent documents and the specific equipment deliverables. The Contractor's security plan shall demonstrate how the physical facilities will be protected using, for example, fencing, controlled access, surveillance equipment, tamper evident packaging, and armed guards.

The Security Plan shall also describe the procedures to be utilized to control the general internal operations of the firm and a description of the facility(ies) in which the work will be performed, including any subcontractors. The Security Plan shall also describe the Contractor's process for conducting background investigations for all employees and subcontractors who will have access to the development, manufacturing and storage of the product.

This plan shall include the security measures to be used to protect the ventilators to be stored at the Contractor's facility (e.g., alarm systems, backup electrical power generator systems, etc.), and the contingency plan (including any backup or redundant facilities) to accommodate any manufacturing and storage problems caused by natural or man-made disasters, power loss, refrigerant loss, equipment failures, etc. The contingency plan shall include a description of the timeline for restarting production.

ARTICLE H.20. CARE OF LIVE VERTEBRATE ANIMALS, HHSAR 352.270-5(b) (October 2009)

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

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

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

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

Note: The Contractor may request registration of its facility and a current listing of licensed dealers from the Regional Office of the Animal and Plant Health Inspection Service (APHIS), USDA, for the region in which its research facility is located. The location of the appropriate APHIS Regional Office, as well as information concerning this program may be obtained by contacting the Animal Care Staff, USDA/APHIS, 4700 River Road, Riverdale, Maryland 20737 (E-mail: [redacted]@aphis.usda.gov ; Web site: (http://www.aphis.usda.gov/animal_welfare).

(End of Clause)

ARTICLE H.21. ANIMAL WELFARE

All research involving live, vertebrate animals shall be conducted in accordance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy). The PHS Policy can be accessed at: http://grants1.nih.gov/grants/olaw/references/phspol.htm

ARTICLE H.22. RESTRICTION ON PORNOGRAPHY ON COMPUTER NETWORKS

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

ARTICLE H.23. GUN CONTROL

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

ARTICLE H.24. CERTIFICATION OF FILING AND PAYMENT OF TAXES

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

ARTICLE H.25. KEY PERSONNEL, HHSAR 352.242-70 (January 2006)

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

(End of Clause)

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

Jeffrey Kepler, Project Manager, Philips Healthcare
Eric Jones, Project Manager, Philips Healthcare
Kathy Stofko, Engineer, Philips Healthcare

PART II - CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

ARTICLE I.1. GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT (BASE PERIOD)

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

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

FAR CLAUSE NO.	DATE	TITLE
52.202-1	Nov 2013	Definitions (Over the Simplified Acquisition Threshold)
52.203-3	Apr 1984	Gratuities (Over the Simplified Acquisition Threshold)
52.203-5	May 2014	Covenant Against Contingent Fees (Over the Simplified Acquisition Threshold)
52.203-6	Sep 2006	Restrictions on Subcontractor Sales to the Government (Over the Simplified Acquisition Threshold)
52.203-7	May 2014	Anti-Kickback Procedures (Over the Simplified Acquisition Threshold)
52.203-8	May 2014	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Over the Simplified Acquisition Threshold)
52.203-10	May 2014	Price or Fee Adjustment for Illegal or Improper Activity (Over the Simplified Acquisition Threshold)
52.203-12	Oct 2010	Limitation on Payments to Influence Certain Federal Transactions (Over $150,000)
52.203-17	Apr 2014	Contractor Employee Whistleblower Rights and Requirements to Inform Employees of Whistleblower Rights (Over the Simplified Acquisition Threshold)
52.204-4	May 2011	Printed or Copied Double-Sided on Postconsumer Fiber Content Paper(Over the Simplified Acquisition Threshold)
52.204-10	Jul 2013	Reporting Executive Compensation and First-Tier Subcontract Awards ($25,000 or more)
52.204-13	Jul 2013	System for Award Management Maintenance
52.209-6	Aug 2013	Protecting the Government's Interest When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (Over $30,000)

FAR CLAUSE NO.	DATE	TITLE
52.215-2	Oct 2010	Audit and Records - Negotiation [Note: Applies to ALL contracts funded in whole or in part with Recovery Act funds, regardless of dollar value, AND contracts over the Simplified Acquisition Threshold funded exclusively with non-Recovery Act funds.]
52.215-8	Oct 1997	Order of Precedence - Uniform Contract Format
52.215-10	Aug 2011	Price Reduction for Defective Certified Cost or Pricing Data (Over $700,000)
52.215-12	Oct 2010	Subcontractor Cost or Pricing Data (Over $700,000)
52.215-14	Oct 2010	Integrity of Unit Prices (Over the Simplified Acquisition Threshold)
52.215-15	Oct 2010	Pension Adjustments and Asset Reversions (Over $700,000)
52.215-18	Jul 2005	Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) other than Pensions
52.215-19	Oct 1997	Notification of Ownership Changes
52.215-21	Oct 2010	Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data - Modifications
52.215-23	Oct 2009	Limitations on Pass-Through Charges (Over the Simplified Acquisition Threshold)
52.216-7	Jun 2013	Allowable Cost and Payment
52.216-8	Jun 2011	Fixed Fee
52.219-8	May 2014	Utilization of Small Business Concerns (Over the Simplified Acquisition Threshold)
52.219-9	Jul 2013	Small Business Subcontracting Plan (Over $650,000, $1.5 million for Construction)
52.219-16	Jan 1999	Liquidated Damages - Subcontracting Plan (Over $650,000, $1.5 million for Construction)
52.222-2	Jul 1990	Payment for Overtime Premium (Over the Simplified Acquisition Threshold) (Note: The dollar amount in paragraph (a) of this clause is $0 unless otherwise specified in the contract.)
52.222-3	Jun 2003	Convict Labor
52.222-21	Feb 1999	Prohibition of Segregated Facilities

FAR CLAUSE NO.	DATE	TITLE
52.222-26	Mar 2007	Equal Opportunity
52.222-35	Jul 2014	Equal Opportunity for Veterans ($100,000 or more)
52.222-36	Jul 2014	Equal Opportunity for Workers with Disabilities
52.222-37	Jul 2014	Employment Reports on Veterans ($100,000 or more)
52.222-40	Dec 2010	Notification of Employee Rights Under the National Labor Relations Act (Over the Simplified Acquisition Threshold)
52.222-50	Feb 2009	Combating Trafficking in Persons
52.222-54	Aug 2013	Employment Eligibility Verification (Over the Simplified Acquisition Threshold)
52.223-6	May 2001	Drug-Free Workplace
52.223-18	Aug 2011	Encouraging Contractor Policies to Ban Text Messaging While Driving
52.225-1	May 2014	Buy American - Supplies
52.225-13	Jun 2008	Restrictions on Certain Foreign Purchases
52.227-1	Dec 2007	Authorization and Consent, Alternate I (Apr 1984)
52.227-2	Dec 2007	Notice and Assistance Regarding Patent and Copyright Infringement
52.227-11	May 2014	Patent Rights - Ownership by the Contractor (Note: In accordance with FAR 27.303(b)(2), paragraph (e) is modified to include the requirements in FAR 27.303(b)(2)(i) through (iv). The frequency of reporting in (i) is annual.
52.227-14	May 2014	Rights in Data - General
52.232-9	Apr 1984	Limitation on Withholding of Payments
52.232-17	May 2014	Interest (Over the Simplified Acquisition Threshold)
52.232-20	Apr 1984	Limitation of Cost
52.232-23	May 2014	Assignment of Claims
52.232-25	Jul 2013	Prompt Payment, Alternate I (Feb 2002)
52.232-33	Jul 2013	Payment by Electronic Funds Transfer--System for Award Management
52.232-39	Jun 2013	Unenforceability of Unauthorized Obligations
52.233-1	May 2014	Disputes

FAR CLAUSE NO.	DATE	TITLE
52.233-3	Aug 1996	Protest After Award, Alternate I (Jun 1985)
52.233-4	Oct 2004	Applicable Law for Breach of Contract Claim
52.242-1	Apr 1984	Notice of Intent to Disallow Costs
52.242-3	May 2001	Penalties for Unallowable Costs (Over $700,000)
52.242-4	Jan 1997	Certification of Final Indirect Costs
52.242-13	Jul 1995	Bankruptcy (Over the Simplified Acquisition Threshold)
52.243-2	Aug 1987	Changes - Cost Reimbursement, Alternate V (Apr 1984)
52.244-2	Oct 2010	Subcontracts (Over the Simplified Acquisition Threshold), Alternate I (June 2007)
52.244-5	Dec 1996	Competition in Subcontracting (Over the Simplified Acquisition Threshold)
52.244-6	Jul 2014	Subcontracts for Commercial Items
52.245-1	Apr 2012	Government Property
52.245-9	Apr 2012	Use and Charges
52.246-23	Feb 1997	Limitation of Liability (Over the Simplified Acquisition Threshold)
52.249-6	May 2004	Termination (Cost-Reimbursement)
52.249-14	Apr 1984	Excusable Delays
52.253-1	Jan 1991	Computer Generated Forms

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

HHSAR CLAUSE NO.	DATE	TITLE
352.202-1	Jan 2006	Definitions - with Alternate paragraph (h) (Jan 2006)
352.203-70	Mar 2012	Anti-Lobbying
352.216-70	Jan 2006	Additional Cost Principles
352.222-70	Jan 2010	Contractor Cooperation in Equal Employment Opportunity Investigations
352.227-70	Jan 2006	Publications and Publicity

HHSAR CLAUSE NO.	DATE	TITLE
352.228-7	Dec 1991	Insurance - Liability to Third Persons
352.233-71	Jan 2006	Litigation and Claims
352.242-70	Jan 2006	Key Personnel
352.242-73	Jan 2006	Withholding of Contract Payments
352.242-74	Apr 1984	Final Decisions on Audit Findings

ARTICLE I.2. AUTHORIZED SUBSTITUTION OF CLAUSES

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

Alternate I (October 1997) of FAR Clause **52.215-14, Integrity of Unit Prices** (October 2010) is added.

FAR Clause **52.216-8, Fixed Fee** (June 2011), is deleted in its entirety and FAR Clause 52.216-11, **Cost Contract--No Fee** (April 1984) is substituted therefor.

ARTICLE I.3. GENERAL CLAUSES FOR A NEGOTIATED FIXED-PRICE SUPPLY CONTRACT (Applicable only if Option is exercised)

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

FAR CLAUSE NO.	DATE	TITLE
52.202-1	Nov 2013	Definitions (Over the Simplified Acquisition Threshold)
52.203-3	Apr 1984	Gratuities (Over the Simplified Acquisition Threshold)
52.203-5	May 2014	Covenant Against Contingent Fees (Over the Simplified Acquisition Threshold)
52.203-6	Sep 2006	Restrictions on Subcontractor Sales to the Government (Over the Simplified Acquisition Threshold)
52.203-7	May 2014	Anti-Kickback Procedures (Over the Simplified Acquisition Threshold)
52.203-8	May 2014	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Over the Simplified Acquisition Threshold)
52.203-10	May 2014	Price or Fee Adjustment for Illegal or Improper Activity (Over the Simplified Acquisition Threshold)
52.203-12	Oct 2010	Limitation on Payments to Influence Certain Federal Transactions (Over $150,000)

FAR CLAUSE NO.	DATE	TITLE
52.203-17	Apr 2014	Contractor Employee Whistleblower Rights and Requirements to Inform Employees of Whistleblower Rights (Over the Simplified Acquisition Threshold)
52.204-4	May 2011	Printed or Copied Double-Sided on Postconsumer Fiber Content Paper(Over the Simplified Acquisition Threshold)
52.204-10	Jul 2013	Reporting Executive Compensation and First-Tier Subcontract Awards ($25,000 or more)
52.204-13	Jul 2013	System for Award Management Maintenance
52.209-6	Aug 2013	Protecting the Government's Interest When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (Over $30,000)
52.211-5	Aug 2000	Material Requirements
52.215-2	Oct 2010	Audit and Records - Negotiation [Note: Applies to ALL contracts funded in whole or in part with Recovery Act funds, regardless of dollar value, AND contracts over the Simplified Acquisition Threshold funded exclusively with non-Recovery Act funds.]
52.215-8	Oct 1997	Order of Precedence - Uniform Contract Format
52.215-10	Aug 2011	Price Reduction for Defective Certified Cost or Pricing Data (Over $700,000)
52.215-12	Oct 2010	Subcontractor Cost or Pricing Data (Over $700,000)
52.215-14	Oct 2010	Integrity of Unit Prices (Over the Simplified Acquisition Threshold)
52.215-15	Oct 2010	Pension Adjustments and Asset Reversions (Over $700,000)
52.215-18	Jul 2005	Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) other than Pensions
52.215-19	Oct 1997	Notification of Ownership Changes
52.215-21	Oct 2010	Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data - Modifications
52.219-8	May 2014	Utilization of Small Business Concerns (Over the Simplified Acquisition Threshold)
52.219-9	Jul 2013	Small Business Subcontracting Plan (Over $650,000, $1.5 million for Construction)
52.219-16	Jan 1999	Liquidated Damages - Subcontracting Plan (Over $650,000, $1.5 million for Construction)

FAR CLAUSE NO.	DATE	TITLE
52.222-19	Jan 2014	Child Labor--Cooperation with Authorities and Remedies
52.222-20	May 2014	Contracts for Materials, Supplies, Articles, and Equipment Exceeding $15,000
52.222-21	Feb 1999	Prohibition of Segregated Facilities
52.222-26	Mar 2007	Equal Opportunity
52.222-35	Jul 2014	Equal Opportunity for Veterans ($100,000 or more)
52.222-36	Jul 2014	Equal Opportunity for Workers with Disabilities
52.222-37	Jul 2014	Employment Reports on Veterans ($100,000 or more)
52.222-40	Dec 2010	Notification of Employee Rights Under the National Labor Relations Act (Over the Simplified Acquisition Threshold)
52.222-50	Feb 2009	Combating Trafficking in Persons
52.222-54	Aug 2013	Employment Eligibility Verification (Over the Simplified Acquisition Threshold)
52.223-6	May 2001	Drug-Free Workplace
52.223-18	Aug 2011	Encouraging Contractor Policies to Ban Text Messaging While Driving
52.225-1	May 2014	Buy American - Supplies
52.225-13	Jun 2008	Restrictions on Certain Foreign Purchases
52.227-1	Dec 2007	Authorization and Consent
52.227-2	Dec 2007	Notice and Assistance Regarding Patent and Copyright Infringement
52.229-3	Feb 2013	Federal, State and Local Taxes (Over the Simplified Acquisition Threshold)
52.232-1	Apr 1984	Payments
52.232-8	Feb 2002	Discounts for Prompt Payment
52.232-9	Apr 1984	Limitation on Withholding of Payments
52.232-11	Apr 1984	Extras
52.232-17	May 2014	Interest (Over the Simplified Acquisition Threshold)
52.232-23	May 2014	Assignment of Claims
52.232-25	Jul 2013	Prompt Payment

FAR CLAUSE NO.	DATE	TITLE
52.232-33	Jul 2013	Payment by Electronic Funds Transfer--System for Award Management
52.232-39	Jun 2013	Unenforceability of Unauthorized Obligations
52.233-1	May 2014	Disputes
52.233-3	Aug 1996	Protest After Award
52.233-4	Oct 2004	Applicable Law for Breach of Contract Claim
52.242-13	Jul 1995	Bankruptcy (Over the Simplified Acquisition Threshold)
52.243-1	Aug 1987	Changes - Fixed-Price
52.244-6	Jul 2014	Subcontracts for Commercial Items
52.249-2	Apr 2012	Termination for the Convenience of the Government (Fixed-Price)
52.249-8	Apr 1984	Default (Fixed-Price Supply and Service)(Over the Simplified Acquisition Threshold)
52.253-1	Jan 1991	Computer Generated Forms

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

HHSAR CLAUSE NO.	DATE	TITLE
352.202-1	Jan 2006	Definitions
352.203-70	Mar 2012	Anti-Lobbying
352.222-70	Jan 2010	Contractor Cooperation in Equal Employment Opportunity Investigations
352.227-70	Jan 2006	Publications and Publicity
352.231-71	Jan 2001	Pricing of Adjustments
352.242-70	Jan 2006	Key Personnel
352.242-73	Jan 2006	Withholding of Contract Payments

ARTICLE I.4. AUTHORIZED SUBSTITUTION OF CLAUSES (only if Option is exercised)

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

a. **Alternate II** (April 1984) of FAR Clause **52.243-1, Changes, Fixed Price** (August 1987), is added.

ARTICLE I.5. ADDITIONAL CONTRACT CLAUSES (applicable to both Base Period and Option)

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

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

1. FAR Clause **52.203-13, Contractor Code of Business Ethics and Conduct** (April 2010).
2. FAR Clause **52.203-14, Display of Hotline Poster(s)** (December 2007).
   "....(3) Any required posters may be obtained as follows:

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

3. FAR Clause **52.210-1, Market Research** (April 2011)
4. FAR Clause **52.217-7, Option for Increased Quantity - Separately Priced Line Item** (March 1989).
   "....The Contracting Officer may exercise the option by written notice to the Contractor within **90 days from Contract Expiration**...."
5. FAR Clause **52.219-28, Post-Award Small Business Program Rerepresentation** (July 2013).
6. FAR Clause **52.223-15, Energy Efficiency in Energy-Consuming Products** (December 2007).
7. FAR Clause **52.224-1, Privacy Act Notification** (April 1984).
8. FAR Clause **52.224-2, Privacy Act**
9. FAR Clause **52.227-14, Rights in Data - General** (May 2014).

   Alternate II (December 2007), FAR Clause **52.227-14, Rights in Data--General** (May 2014).

   Alternate III (December 2007), FAR Clause **52.227-14, Rights in Data--General** (May 2014).

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

1. HHSAR Clause **352.201-70, Paperwork Reduction Act** (January 2006).
2. HHSAR Clause **352.223-70, Safety and Health** (January 2006).
3. HHSAR Clause **352.231-70, Salary Rate Limitation** (August 2012).

   Note: *P.L. 113-76 sets forth the Salary Rate Limitation at the Executive Level II Rate, effective January 17, 2014.*

   See the following Web site for Executive Schedule rates of pay: http://www.opm.gov/oca/ .

   (For current year rates, click on Salaries and Wages/Executive Schedule/Rates of Pay for the Executive Schedule. For prior year rates, click on Salaries and Wages/select Another Year at the top of the page/Executive Schedule/Rates of Pay for the Executive Schedule. Rates are effective January 1 of each calendar year unless otherwise noted.)

ARTICLE I.6. ADDITIONAL FAR CONTRACT CLAUSES INCLUDED IN FULL TEXT (applicable to both Base Period and Option)

This contract incorporates the following clauses in full text.

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

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

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

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

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

   1. The non-public segment, into which Government officials and the Contractor post information, which can only be viewed by--
      i. Government personnel and authorized users performing business on behalf of the Government; or
      ii. The Contractor, when viewing data on itself; and
   2. The publicly-available segment, to which all data in the non-public segment of FAPIIS is automatically transferred after a waiting period of 14 calendar days, except for--
      i. Past performance reviews required by subpart 42.15;
      ii. Information that was entered prior to April 15, 2011; or
      iii. Information that is withdrawn during the 14-calendar-day waiting period by the Government official who posted it in accordance with paragraph (c)(1) of this clause.

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

   1. If the Contractor asserts in writing within 7 calendar days, to the Government official who posted the information, that some of the information posted to the non-public segment of FAPIIS is covered by a disclosure exemption under the Freedom of Information Act, the Government official who posted the information must within 7 calendar days remove the posting from FAPIIS and resolve the issue in accordance with agency Freedom of Information procedures, prior to reposting the releasable information. The contractor must cite 52.209-9 and request removal within 7 calendar days of the posting to FAPIIS.
   2. The Contractor will also have an opportunity to post comments regarding information that has been posted by the Government. The comments will be retained as long as the

associated information is retained, i.e., for a total period of 6 years. Contractor comments will remain a part of the record unless the Contractor revises them.

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

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

(End of clause)

PART III

SECTION J – LIST ATTACHMENTS

The following documents are attached and incorporated in this contract:

1. Statement of Work, dated 5/28/2014, 43 pages.

2. Invoice/Financing Request Instructions and Contract Financial Reporting Instructions for BARDA Cost-Reimbursement Type Contracts, 6 pages.

3. Financial Report of Individual Project/Contract, 1 page.

4. Instructions for Completing Financial Report of Individual Project/Contract, 3 pages.

5. Safety and Health, HHSAR Clause 352.223-70, dated 1/2006, 2 pages.

6. Disclosure of Lobbying Activities, SF-LLL, dated 7/1997, 2 pages.
   Located at: http://www.whitehouse.gov/sites/default/files/omb/grants/sfllin.pdf .

7. Report of Government Owned, Contractor Held Property, dated 3/08, 1 page.
   Located at: http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/Govt-Owned-Prop.pdf .

8. Small Business Subcontracting Plan, dated 3/31/2014, 15 pages.

9. Ventilator Warranty Statement, dated 5/28/2014, 1 page.

10. Contract Performance Reports (EVM):
    Format 1: Work Breakdown Structure,
    http://www.dtic.mil/whs/directives/infomgt/forms/eforms/dd2734-1.pdf
    Format 2: Organizational Categories,
    http:/www.dtic.mil/whs/directives/infomgt/forms/eforms/dd2734-2.pdf
    Format 3: Baseline
    http://www.dtic.mil/whs/directives/infomgt/forms/eforms/dd2734-3.pdf
    Format 4: Staffing
    http://www.dtic.mil/whs/directives/infomgt/forms/eforms/dd2734-4.pdf
    Format 5: Explanations and Problem Analyses
    http://www.dtic.mil/whs/directives/infomgt/forms/eforms/dd2734-5.pdf

PART IV

SECTION K - REPRESENTATIONS AND CERTIFICATIONS

The following documents are incorporated by reference in this contract:

1. Annual Representations and Certifications completed and located in the Online Representations and Certifications Application (ORCA) at The System for Acquisition Management (SAM) website (http://www.sam.gov).

2. IRB Registration, Office of Human Research Protections (OHRP)

Institution / Organization Name	IRB Number	OORG Number
Western Institutional Review Board (WIRB)	IRB00000533	IORG0000432
New England Institutional Review Board (NEIRB)	IRB00005806 and IRB00000755	IORG0000444
Allendale Institutional Review Board (AIRB)	IRB00005829	IORG0004889

END of the SCHEDULE
(CONTRACT)