AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE		PAGE 1 OF PAGES 10	
2. AMENDMENT/MODIFICAITON NO. Amendment # 04	3. EFFECTIVE DATE see block 16C	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. (If applicble)
6. ISSUED BY CODE		7. ADMINISTERED BY (If other than Item 6) CODE	

HHS/OS/ASPR/BARDA
330 Independence Ave. S.W. Room G640
Washington, D.C. 202021

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

N/A

CODE | FACILITY CODE

(X) 9A. AMENDMENT OF SOLICIATION NO. RFP-BARDA-08-15

9B. DATED (SEE ITEM 11) 02/28/2008

10A. MODIFICATION OF CONTRACT/ORDER NO.

10B. DATED (SEE ITEM 13)

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers ☐ is extended, ☒ is not extended.

Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a)By completing items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment your desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)

13. THIS ITEM ONLY APPLIES TO MODIFICATION OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

CHECK ONE	
☐	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
☐	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
☐	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
☐	D. OTHER (Specify type of modification and authority)

E. IMPORTANT: Contractor ☒ is not, ☐ is required to sign this document and return _____ copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)

The RFP is amended to change sections B, C, F, L, and M of the solicitation to address 2 advance understandings and the required earned value management system (EVMS) as reflected on pages 2-10.

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) Brian K. Goodger	
15B. CONTRACTOR/OFFEROR (Signature of person authorized to sign)	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA Brian K. Goodger (Signature of Contracting Officer)	16C. DATE SIGNED 6/30/08

The RFP is hereby amended to reflect the following changes:

Section B – Supplies or Service and Price/Costs

Page 6
Original:
B.5. Advance Understandings
a. Inspections & Collection of Samples

At the discretion of the USG and independent of testing conducted by the Contractor, the USG reserves the right to conduct site visits and collect samples of product held by the Contractor and in the SNS.

Changed to:
a. Inspections & Collection of Samples

At the discretion of the USG and independent of testing conducted by the Contractor, the USG reserves the right to conduct site visits and collect samples of product held by the Contractor, and subcontract (by approval of the Prime Contractor with optional attendance by the Prime Contractor of the subcontractor's facility), and in the SNS.

Original:
B.5. Advance Understandings
d. Reserved

Changed to:
d. Uniform Cost Assumption

For cost proposal purposes, the government is providing an assumption to the cost of development and implementation of an earned valued management system (EVMS) between $500,000 and $2,500,000 for the life of this contract. Should the offeror already have an EVMS in place and therefore only need implementation of the EVMS the cost should be significantly lower. The EVMS costs should be incorporated into your FFP per dose in CLIN 0001A. An Offeror who proposes EVMS costs outside the uniform cost assumption should provide justification in their proposal.

The successful offeror shall employ their EVMS during contract performance in CLIN 0001A & 0001B.

Section C. Statement Of Objectives (SOO)

Page 11
Original:
C.7. Project Management & Risk Mitigation Objectives

C.7.1. The offeror(s) shall develop an integrated project plan (tabular and Gantt form) that clearly indicates the critical path to support an EUA, and licensure. Attention should be placed on the amount of time that will be needed by the USG (BARDA, FDA, CDC) for review of critical documentation. The contractor shall integrate to demonstrate interdependencies and the plan will be used to monitor performance of the contract. The Contractor's project plan shall be incorporated into the contract.

1. Work breakdown structure (WBS) shall be at level 5 for the overall plan and level 6 for manufacturing.

C.7.2. The offeror(s) shall develop a risk mitigation plan highlighting potential problems and/or issues that may arise during the life of the contract, their impact on cost, performance and timelines, and appropriate remediation plans.

C.7.3. The offeror(s) shall develop an Earned Value Management system, or similar plan, to monitor cost against schedule by task. Plan shall include a USG-Contractor Integrated Baseline Review (IBR).

C.7.4. The offeror(s) shall participate in regular meetings to coordinate and oversee the contracting effort as requested by the Project Officer. Such meetings may include, but are not limited to, meetings of all Contractors and Subcontractors to discuss study designs, site visits to the Contractor's facilities, and meetings with individual Contractors and other HHS officials to discuss the technical, regulatory, and ethical aspects of the program. The Contractor shall provide data, reports, and presentations to groups of outside experts and USG personnel as required by the Project Officer in order to facilitate review of contract activities.

Changed to:

C.7.1. Integrated Master Plan

The offeror(s) shall submit an Integrated Master Project Plan (including tabular and Gantt forms) that clearly indicate the critical path to support an EUA and licensure. Attention should be placed on the amount of time that will be needed by the USG (BARDA, FDA, CDC) for review of critical documentation. The offeror shall integrate to demonstrate interdependencies between CLINS 0001A and 0001B. The Integrated Master Project Plan shall be incorporated into the contract, and will be used to monitor performance of the contract.

C.7.1.1 Work Breakdown Structure

Offeror(s) shall submit a Work Breakdown Structures (WBS) to Level 5 as part of their project plan. The WBS shall be discernable and consistent. BARDA may require an offeror/contractor to furnish WBS data at the work package level or at a lower level if there is significant complexity and risk associated with the task. The WBS shall be product and/or deliverable based where possible. MIL-HDBK-881A may be referenced as guidance in the creation of the WBS (see http://www.acq.osd.mil/pm/).

C.7.2. Risk Management Plan

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

C.7.3. Earned Value Management System Plan

The offeror(s) shall propose use of an Earned Value Management System (EVMS) in the management of this contract that is consistent with ANSI/EIA-STD-748 guidelines. EVMS shall be applied to CLINS 0001A and 0001B As part of the Integrated Master Project Plan required in Section C.7.1., the offeror(s) shall submit a written summary of the management procedures that it will establish, maintain and use to comply with EVMS requirements to include the following topics:

C.7.3.1. Integrated Baseline Review

The offeror(s) shall submit a plan for an Integrated Baseline Review to occur within 90 days of contract award. At the IBR, the Contractor and BARDA shall mutually agree upon cost, schedule and technical plan baselines (Performance Measurement Baseline). These baselines shall be the basis for monitoring and reporting progress throughout the life of the contract. The IBR is conducted to achieve confidence that the baselines accurately capture the entire technical scope of work, are consistent with contract schedule requirements, are reasonably and logically planned, and have adequate resources assigned. A separate IBR shall be conducted for each CLIN where EVMS will be applied.

C.7.3.2. Integrated Master Schedule

The offeror(s) shall deliver an initial program level Integrated Master Schedule (IMS), derived from the Integrated Master Project Plan that rolls up all time-phased WBS elements down to the activity level. This IMS shall include the dependencies that exist between tasks. This IMS will be agreed to and finalized at the IBR. DI-MGMT-81650 may be referenced as guidance in the creation of the IMS (see http://www.acq.osd.mil/pm/).

C.7.3.3 Earned Value Contract Performance Report (EV-CPR)

The Contractor shall deliver an Earned Value Contract Performance Report on a monthly basis per the instruction in DI-MGMT-81466A (see http://www.acq.osd.mil/pm/). Contractor shall provide Format 1 and Format 5 only. Format 1 will be reported at the Work Breakdown Structure level agreed to by BARDA and the Contractor at the IBR. Format 1 may be reported using either costs or in Equivalent Units. When using Equivalent Units, the budgeted value (BCWS) is based on a per unit value. The units earned or accomplished and the budgeted per unit value determine the value earned.

EV Variance thresholds will be negotiated with the Contractor post-award but for planning purposes will likely be (+/- 10%). In conjunction with the CPR, the Contractor shall provide a monthly update to the IMS with up to date performance data and should include actual start/finish and projected start/finish dates.

C.7.4. The offeror(s) shall participate in regular meetings to coordinate and oversee the contracting effort as requested by the Project Officer. Such meetings may include, but are not limited to, meetings of all Contractors and Subcontractors to discuss study designs, site visits to the Contractor's facilities, and meetings with individual Contractors and other HHS officials to discuss the technical, regulatory, and ethical aspects of the program. The Contractor shall provide data, reports, and presentations to groups of outside experts and USG personnel as required by the Project Officer in order to facilitate review of contract activities.

Section F - Deliveries or Performance

Page 14-15
Original:
F.3. Contract Deliverables

a. The following deliverables are applicable to CLIN 0001: 25,000,000 doses of rPA in accordance with the delivery schedule in C.9.
b. In accordance with Section C.7.1 , an Integrated Project Plan (IPP), a Work Breakdown Structure (WBS) in tabular form clearly indicating critical path milestones to fulfill requirements for EUA and licensure and a complete Gantt chart for the entire SOO to WBS level 5.
c. In accordance with Section C.4.4, a Phase 4 post-marketing plan
d. In accordance with Section C.5.3, a Quality Control/Quality Assurance Monitoring Plan
e. In accordance with Section C.7.2, a Risk Management Plan
f. In accordance with Section C.7.3, a Earned Value Management Plan
g. In accordance with Section H.8, a Security Plan
h. In accordance with Section H.9, a Office of Human Research Protections (OHRP) approved assurance of compliance
i. In accordance with Section H.11, a written Animal Welfare Assurance with the Office for Laboratory Animal Welfare (OLAW).
j. In accordance with Section H. 12, evidence of registration with the Secretary of Agriculture of the United States in accordance with 7 U.S.C. 2316 and 9 CFR Section 2.30.
k. In accordance with Section H.14, for prime or subcontract awards to domestic institutions that possess, use, and/or transfer Select Agents under this contract, final CDC Select Agent registration certificate(s)
l. In accordance with Section H.14, for prime or subcontract awards to foreign institutions that possess, use, and/or transfer Select Agents under this contract, the foreign institution must provide information satisfactory to BARDA, that safety, security, and training standards equivalent to those described (in 42 CFR part 73, 7 CFR part 331, and/or 9 CFR part 121 at: http://www.aphis.usda.gov/programs/ag_selectagent/FinalRule3-18-05.pdf) are in place.
m. See F.4.
n. Reserved.

Changed to:
F.3. Contract Deliverables

a. The following deliverables are applicable to CLIN 0001: 25,000,000 doses of rPA in accordance with the delivery schedule in C.9.

b. *In accordance with Section C.7.1 , an Integrated Master Project Plan, a Work Breakdown Structure (WBS) in tabular form clearly indicating critical path milestones to fulfill requirements for EUA and licensure and a complete Gantt chart for the entire SOO to WBS level 5.*
c. *In accordance with Section C.4.4, a Phase 4 post-marketing plan*
d. *In accordance with Section C.5.3, a Quality Control/Quality Assurance Monitoring Plan*
e. *In accordance with Section C.7.2, a Risk Management Plan*
f. *In accordance with Section C.7.3, a Earned Value Management System Plan, including Integrated Master Schedule*
g. *In accordance with Section H.8, a Security Plan*
h. *In accordance with Section H.9, a Office of Human Research Protections (OHRP) approved assurance of compliance*
i. *In accordance with Section H.11, a written Animal Welfare Assurance with the Office for Laboratory Animal Welfare (OLAW).*
j. *In accordance with Section H. 12, evidence of registration with the Secretary of Agriculture of the United States in accordance with 7 U.S.C. 2316 and 9 CFR Section 2.30.*
k. *In accordance with Section H.14, for prime or subcontract awards to domestic institutions that possess, use, and/or transfer Select Agents under this contract, final CDC Select Agent registration certificate(s)*
l. *In accordance with Section H.14, for prime or subcontract awards to foreign institutions that possess, use, and/or transfer Select Agents under this contract, the foreign institution must provide information satisfactory to BARDA, that safety, security, and training standards equivalent to those described (in 42 CFR part 73, 7 CFR part 331, and/or 9 CFR part 121 at: http://www.aphis.usda.gov/programs/ag_selectagent/FinalRule3-18-05.pdf) are in place.*
m. *See F.4.*
n. *Reserved.*

Page 15-16
Original:
F.4. Reporting Requirements

1. Monthly Reports

On the tenth of each month for the previous calendar month, the contractor shall submit a Monthly Technical Progress Report to the Project Officer and the Contracting Officer. The contractor shall submit one copy of the Monthly Progress Report electronically via e-mail. A monthly report will not be required for the period when the final report is due. Any attachments to the e-mail report shall be submitted in Microsoft Word, Excel, Project, or compatible versions. Such reports shall include the following specific information: The contract number and title, the period of performance being reported, the contractor's name and address, the author(s), and the date of submission.

The Monthly Technical Progress Report shall include an Executive Summary in MS PowerPoint format, highlighting the progress, issues, and actions relevant to: manufacturing, non-clinical, clinical, regulatory, and security. The Executive summary should be limited to 2-3 slides and only highlight critical issues for that reporting period. The Monthly Technical Progress report shall address each of the below items and be cross-referenced to the Critical Path Gantt Chart, Earned Value Management, WBS/Project Plan and the Risk Mitigation plan.

The report shall detail the planned progress and actual progress during the period covered, explaining why any differences between the two occurred, and if behind schedule what corrective steps and actions

are planned. The project's plans and schedule must reflect FDA regulatory requirements and guidance.

These reports are subject to the technical inspection and requests for clarification by the Project Officer. These reports shall be brief and factual and provide the following information:

a. Progress in assay development and validation, and process development and validation of BDS and FDP manufacture to support scale-up to full production capacity, including raw material procurement status.
b. Quality control/quality assurance monitoring.
c. FDA/CBER inspections and consultation results or recommendations.
d. Storage and stability studies for expiration date results (accelerated, stress, and long-term storage conditions).
e. Security assessment, problems, and recommendations.
f. Progress, results, and final reports of expanded human safety studies.
g. Progress, results, and final reports of efficacy studies performed in animals if following the Animal Rule, or clinical studies required for Accelerated FDA/CBER Approval.
h. Progress, results, and final reports of any other studies deemed necessary by FDA/CBER.
i. Progress in providing data to CDC to support an EUA.
j. Progress in obtaining FDA/CBER approval/licensure for post-exposure prophylaxis, concomitant with antibiotics (PEP), in adults considered to be at risk subsequent to a known or suspected anthrax release. In addition, for general use prophylaxis (GUP) of healthy individuals considered to be at risk to anthrax exposure.
k. Progress in execution of any product disposition directions provided by the USG.
l. Progress, results, and final reports of any necessary additional animal and human studies to obtain expanded labeling in special populations, including pediatric and geriatric populations;
m. Potency and stability testing results.
n. Inventory report of total number of vaccine doses in storage during the month, to include: lot number, expiration date, and bulk quantity (if applicable).

o. Quantity of out-of-date FDP, assessment and recommendations to replacement FDP orders to maintain required stockpile quantities.
p. Physical storage facilities (Contractor and SNS) assessments.
q. Overall project assessment, problems encountered and recommended solutions, etc.

Changed to:
F.4. Reporting Requirements

1. Monthly Reports

Monthly Reports shall be submitted to the Project Officer and Contracting Officer electronically via e-mail on the tenth of the month for the previous calendar month. Any attachments to the e-mail report shall be submitted in Microsoft Word, Excel, Project, or compatible versions. Such reports shall include the following specific information: The contract number and title, the period of performance being reported, the contractor's name and address, the author(s), and the date of submission. A monthly report will not be required for the period when the final report is due.

Technical Progress Report:

The Monthly Technical Progress Report shall include an Executive Summary in MS PowerPoint format, highlighting the progress, issues, and actions relevant to: manufacturing, non-clinical, clinical, regulatory, and security. The Executive summary should be limited to 2-3 slides and only highlight critical issues for that reporting period. The Monthly Technical Progress report shall address each of the below items and be cross-referenced to the Integrated Master Project Plan (including WBS), Integrated Master Schedule, Risk Management Plan, and Earned Value Contractor Performance Report.

The report shall detail the planned progress and actual progress during the period covered, explaining why any differences between the two occurred, and if behind schedule what corrective steps and actions are planned. The project's plans and schedule must reflect FDA regulatory requirements and guidance.

These reports are subject to the technical inspection and requests for clarification by the Project Officer. These reports shall be brief and factual and provide the following information:

a. *Progress in assay development and validation, and process development and validation of BDS and FDP manufacture to support scale-up to full production capacity, including raw material procurement status.*
b. *Quality control/quality assurance monitoring.*
c. *FDA/CBER inspections and consultation results or recommendations.*
d. *Storage and stability studies for expiration date results (accelerated, stress, and long-term storage conditions).*
e. *Security assessment, problems, and recommendations.*
f. *Progress, results, and final reports of expanded human safety studies.*
g. *Progress, results, and final reports of efficacy studies performed in animals if following the Animal Rule, or clinical studies required for Accelerated FDA/CBER Approval.*
h. *Progress, results, and final reports of any other studies deemed necessary by FDA/CBER.*
i. *Progress in providing data to CDC to support an EUA.*
j. *Progress in obtaining FDA/CBER approval/licensure for post-exposure prophylaxis, concomitant with antibiotics (PEP), in adults considered to be at risk subsequent to a known or suspected anthrax release. In addition, for general use prophylaxis (GUP) of healthy individuals considered to be at risk to anthrax exposure.*
k. *Progress in execution of any product disposition directions provided by the USG.*
l. *Progress, results, and final reports of any necessary additional animal and human studies to obtain expanded labeling in special populations, including pediatric and geriatric populations;*
m. *Potency and stability testing results.*
n. *Inventory report of total number of vaccine doses in storage during the month, to include: lot number, expiration date, and bulk quantity (if applicable).*
o. *Quantity of out-of-date FDP, assessment and recommendations to replacement FDP orders to maintain required stockpile quantities.*
p. *Physical storage facilities (Contractor and SNS) assessments.*
q. *Overall project assessment, problems encountered and recommended solutions, etc.*

Earned Value Contractor Performance Report:

An EV-CPR will be submitted in accordance with Section C.7.3.3.

Page 17
Original:

8. FDA Submissions and meetings

a. The contractor shall forward the initial draft minutes and final draft minutes of any formal meeting with the FDA to BARDA.

b. The contractor shall forward the final draft minutes of any informal meeting with the FDA to BARDA.

c. The contractor shall forward the dates and times of any meeting with the FDA to BARDA and make arrangements for appropriate BARDA staff to attend FDA meetings.

d. The contractor shall provide BARDA the opportunity to review and comment upon any documents to be submitted to the FDA. The contractor shall provide BARDA with a 72 hour period in which to review and provide comments back to the contractor.

Changed to:

8. FDA Submissions and meetings

a. The contractor shall forward the initial draft minutes and final draft minutes of any formal meeting with the FDA to BARDA.

b. The contractor shall forward the final draft minutes of any informal meeting with the FDA to BARDA.

c. The contractor shall forward the dates and times of any meeting with the FDA to BARDA and make arrangements for appropriate BARDA staff to attend FDA meetings.

d. The contractor shall provide BARDA the opportunity to review and comment upon any documents to be submitted to the FDA. A minimum of three business days shall be required to review and provide comments back to the contractor. In the case of lengthy or complex submissions, BARDA will require five business days for review.

SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

Page 44
Original:

L.23. A Gantt chart presented as an integrated project plan (a copy must also be provided on CD). The Gantt chart must contain sufficient detail to permit reviewers to make a realistic evaluation of the Offeror's likelihood of success.

L.24. A tabular project plan which outlines key, critical path milestones. The project plan should include, but is not limited to, milestones in manufacturing, non-clinical, clinical, regulatory submissions, and delivery of product to the SNS.

L.25. An earned value management, or similar, plan tying cost and schedule to specific task which can be monitored during contract performance.

L.26. A risk mitigation plan. The risk mitigation plan should address potential problems that may arise and remediation plans to circumvent major time disruption to the project. Each of these documents can be revised during negotiations with the successful Offeror and will be incorporated into the contract.

Changed to:

L.23. *An Integrated Master Project Plan which outlines key, critical path milestones and WBS. The plan should include, but is not limited to, milestones in manufacturing, non-clinical, clinical, regulatory submissions, and delivery of product to the SNS.*

L.24. *A Gantt chart presented as an integrated project plan (a copy must also be provided on CD). The Gantt chart must contain sufficient detail to permit reviewers to make a realistic evaluation of the Offeror's likelihood of success.*

L.25. *An earned value management systems plan consistent with ANSI/EIA-STD-748 guidelines, including a preliminary Integrated Master Schedule.*

L.26. *A risk management plan. The risk management plan should address potential problems that may arise and remediation plans to circumvent major time disruption to the project. Each of these documents can be revised during negotiations with the successful Offeror and will be incorporated into the contract.*

SECTION M - EVALUATION FACTORS FOR AWARD

Page 50
Original:

V. Project Management and Risk Mitigation (20 points)

a. Gantt Chart
b. Project Plan
c. Risk Mitigation Plan
d. Earned Value Management Plan

Changed to:

V. Project Management and Risk Mitigation (20 points)

a. Gantt Chart
b. Integrated Master Project Plan
c. Risk Management Plan
d. Earned Value Management System Plan

All Other Terms and Conditions Remain Unchanged