AWARD/CONTRACT	1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)	RATING	PAGE OF PAGES
			1 | 83

2. CONTRACT (Proc. Inst. Ident.) NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQUEST/PROJECT NO.
75A50119C00078	See Block 20C	OS247584

5. ISSUED BY	CODE	6. ADMINISTERED BY (If other than Item 5)	CODE
ASPR-BARDA	ASPR-BARDA	ASPR-BARDA	ASPR-BARDA
200 Independence Ave., S.W.		US DEPT OF HEALTH & HUMAN SERVICES	
Room 640-G		BIOMEDICAL ADVANCED RESEACH & DEVELOPMENT AUT	
Washington DC 20201		200 INDEPENDENCE AVE, S.W.	
		Washington DC 20201	
		SCD-C	

7. NAME AND ADDRESS OF CONTRACTOR (No., street, country, State and ZIP Code)	8. DELIVERY	9. DISCOUNT FOR PROMPT PAYMENT
BECKMAN COULTER INC 138131 Attn: SARAH KEHOE BECKMAN COULTER, INC. 11800 SW 147TH AVE MIAMI FL 331962500	☐ FOB ORIGIN ☒ OTHER (See below)	

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

CODE 138131	FACILITY CODE

11. SHIP TO/MARK FOR	CODE	12. PAYMENT WILL BE MADE BY	CODE
HHS/OS/ASPR	HHS/OS/ASPR	PSC	PSC
200 C St SW		Program Support Center	
WASHINGTON DC 20201		7700 Wisconsin Ave	
		Bethesda MD 20814	

13. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION:	14. ACCOUNTING AND APPROPRIATION DATA
☐ 10 U.S.C. 2304 (c) ( ) ☐ 41 U.S.C. 3304 (a) ( )	2019.1992019.25106

15A. ITEM NO	15B. SUPPLIES/SERVICES	15C. QUANTITY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT
	Continued				
	15G. TOTAL AMOUNT OF CONTRACT				$1,250,000.00

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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* 1 *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 items listed above and on any continuation sheets. This award consummates the contract which consists of the following documents: (a) the Government's solicitation and your 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
CHRISTOPHER P RILEY ; PRESIDENT	TROY G. FRANCIS

19B. NAME OF CONTRACTOR	19C. DATE SIGNED	20B. UNITED STATES OF AMERICA	20C. DATE SIGNED
BY _____ (Signature of person authorized to sign)	9/26/19	BY Troy G. Francis -S (Signature of the Contracting Officer) Digitally signed by Troy G. Francis -S DN: c=US, o=U.S. Government, ou=HHS, ou=OS, ou=People, 0.9.2342.19200300.100.1.1=2001931480, cn=Troy G. Francis -S Date: 2019.09.30 12:03:54 -04'00'	9/30/2019

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STANDARD FORM 26 (Rev. 3/2013)
Prescribed by GSA - FAR (48 CFR) 53.214(a)

NAME OF OFFEROR OR CONTRACTOR

BECKMAN COULTER INC 138131

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	Tax ID Number: 95-1040600 DUNS Number: 091551650 ASPR-19-04264 -(b) (4) Delivery: 09/30/2019 Appr. Yr.: 2019 CAN: 1992019 Object Class: 25106 Period of Performance: 09/30/2019 to 12/31/2021				
1	ASPR-19-04264 -(b) (4) (b) (4) Obligated Amount: (b) (4)				(b) (4)

PART I – THE SCHEDULE

SECTION B – SUPPLIES OR SERVICES AND PRICES/COSTS

B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

The overall objective of this contract (Contract) is to develop and commercialize a solution for the accurate detection and prediction of sepsis. The scope of work for this Contract includes identifying a set of hematology instrument parameters for accurately detecting and predicting sepsis, training and validating a machine learning algorithm which incorporates additional data from medical records to detect and predict sepsis onset up to several days earlier than the current state of the art, and commercializing the solution which incorporates the algorithm as part of a Software as a Medical Device (SaMD) cleared by the Food and Drug Administration (FDA).

The Advanced Research and Development effort will progress in specific stages, including a Base Work Segment (CLIN 0001) and five (5) Option Work Segments (CLINs 0002 – 0006). Work performed during the Base Work Segment and in each of the five (5) Option Work Segments constitutes independent, non-severable discrete work segments that cannot be further subdivided for separate performance. Work specified in each work segment is necessary to support the following:

CLIN 0001 – (b) (4)
CLIN 0002 – (b) (4)
CLIN 0003 – (b) (4)
CLIN 0004 – (b) (4)
CLIN 0005 – (b) (4)
CLIN 0006 – (b) (4)

The Government (which, as used herein, refers to the Biomedical Advanced Research and Development Authority (BARDA)) has determined that it has a Bona Fide Need for each non-severable discrete work segment. That need will be met upon the completion of the defined task(s) listed in the Statement of Work (SOW) for each work segment (See Section J - Attachment 1) and the completion of the Go/No-Go Milestones. Each work segment provides independent merit and value to the Government. Each work segment will be fully funded from an appropriation source that is current at the time the Contract is awarded (Base Work Segment, CLIN 0001) and at the time the Government exercises each Option Work Segment (CLINs 0002 – 0006).

B.2 BASE PERIOD

a. The title of this Contract is "Monocyte Distribution Width (MDW) and Predictive Analytic Algorithms for Sepsis Detection ", in response to BARDA-BAA-18-100-SOL-00003 (Special Instructions – Development Area of Interest #15.1).

b. The Contractor shall maintain records of all contract costs and such records shall be subject to FAR 52.215-2 Audit Records-Negotiation (Oct 2010).

c. It is estimated that the monies currently obligated at the time of contract award will cover performance of the Base Period (CLIN 0001). See chart below:

CLIN	Description	Period of Performance	Total Cost	Contractor Cost-Share (b)	Government Cost (b)
0001	(b) (4)	30 September 2019 - 31 December 2021	(b) (4)	(b) (4)	$1,250,000

B.3. OPTION PERIODS

a. The Contract includes 5 Option Periods (CLINs 0002 – 0006).
b. Pursuant to FAR 52.217-9, Option to Extend the Term of the Contract (Mar 2000), set forth in Section I.3 of this Contract, the Government may, by unilateral contract modification, require the Contractor to perform discrete portions of additional work contained within CLINs 0002 – 0006, as specified in the Statement of Work. See chart below:

CLIN	Description	Period of Performance	Total Cost	Contractor Cost-Share (b)	Government Cost (b)
0002	(b) (4)	01 January 2020 - 30 May 2020	(b) (4)	(b) (4)	$731,858
0003	(b) (4)	01 January 2020 - 30 September 2020	(b) (4)	(b) (4)	$212,459
0004	(b) (4)	01 June 2020 - 01 March 2021	(b) (4)	(b) (4)	$831,234
0005	(b) (4)	01 March 2021 - 30 September 2023	(b) (4)	(b) (4)	$3,803,589
0006	(b) (4)	01 January 2022 - 30 September 2023	(b) (4)	(b) (4)	$920,860

B.4. LIMITATIONS APPLICABLE TO DIRECT COSTS

a. **Items Unallowable Unless Otherwise Provided**

Notwithstanding FAR 52.216-7 Allowable Cost and Payment incorporated into the Contract and unless authorized in writing by the Contracting Officer, the cost of the following items or activities shall be unallowable as direct costs at any level, including subcontracts, for:

1) Personal information technology (IT) computer equipment (e.g., including but not limited to, personal computers; cell phones; tablets; printers; etc.);

2) Acquisition, by purchase or lease, of any interest in real property;

3) Special rearrangement or alteration of facilities;

4) Lease or purchase of any item of general purpose office furniture, office equipment, or personal computers/tablets regardless of dollar value;

5) Attendance at scientific meetings/conferences;

6) Printing Costs (as defined in the Government Printing and Binding Regulations);

7) Overtime (premium) compensation;

8) Entering into certain types of subcontracting arrangements (see Section B.5). Note that most consulting agreements require the Contracting Officer (CO)'s written consent.

9) No travel costs are authorized under this Contract at the prime level as they were negotiated as part of Contractor's cost-share contribution;

10) Refreshment & Meal Expenditures (non-travel related);

11) Consultant Costs (see Section B.5); and

12) Subcontractor costs (see Section B.5).

B.5. ADVANCE UNDERSTANDINGS

a. **Cost Sharing Arrangement**

The Contractor and Government have agreed to enter into a cost-share contract. The Contractor has agreed to pay (b) **of total costs for CLINs 0001 – 0006** over the life of the Contract. This shall be represented by the corresponding amount (b) (4) reduction as stated above per the respective CLIN, to the bottom line of any invoice submitted under performance of this Contract.

b. **Subcontracts and Consultants**

Award of any firm fixed price (FFP) subcontract or FFP consulting agreement in excess of $250,000 or any cost reimbursement subcontract or consulting agreement shall not proceed without the prior written consent of the CO via a Contracting Officer Authorization (COA) Letter. COA letters will only be issued upon review of the supporting documentation required by FAR 52.244-2 Subcontracts. After receiving written consent of the subcontract or consulting agreement by the CO, a copy of the signed, executed subcontract or consulting agreement shall be provided to the CO within ten (10) calendar days of full execution.

c. **Person-in-Plant**

With seven (7) days advance notice to the Contractor in writing from the CO, the Government may place a man-in-plant in the Contractor' or Subcontractor's facility, who shall be subject to the Contractor's or Subcontractor's policies and procedures regarding security and facility access at all times while in the Contractor's or Subcontractor's facility. The Government's representative shall be provided reasonable access, during normal business hours, of the production areas being utilized in performance on the Contract. As determined by federal law, no Government representative shall publish, divulge, disclose, or make known in any manner, or to any extent not authorized by law, any information coming to him in the course of employment or official duties, while stationed in a contractor or subcontractor plant.

An article substantially similar to this Person-in-Plant article shall be incorporated into any subcontract for experimental or manufacturing work.

d. **Quality Assurance (QA) Audits**

The Government reserves the right to participate in QA audits of the Contractor and its vendors for GxP compliance. Upon completion of the QA audit, the Contractor shall provide a report capturing the findings, results, and next steps in proceeding with any potential subcontractors. If action is requested for a subcontractor, detailed corrective and preventative plans for addressing areas of non-conformance to ICH and FDA regulations for GLP, GMP, or GCP guidelines, as identified in the audit report, must be provided to the CO and the Contracting Officer's Representative (the COR) for review and acceptance. The Contractor shall provide responses from the subcontractors

to address these concerns and plans for corrective action. The Contractor shall do the following:

- Contractor shall notify CO and COR of upcoming, ongoing, or recent audits/site visits of subcontractors as part of weekly communications.
- Contractor shall notify the CO and COR within 5 business days of report completion. The Contractor shall complete the report within 60 days of the audit/site visit, or as negotiated with the COR in writing dependent upon the audit findings.

e. **Overtime Compensation**

No overtime (premium) compensation is authorized under the subject contract.

f. **Sharing of contract deliverables within United States Government (USG)**

In an effort to build a robust medical countermeasure pipeline through increased collaboration, the Government may share technical deliverables with Government entities responsible for Medical Countermeasure Development. In accordance with recommendations from the Public Health Emergency Medical Countermeasure Enterprise (PHEMCE) Review, agreements established in the Integrated Portfolio Advisory Committee (PAC) Charter, and agreements between BARDA and the Department of Defense, the National Institutes of Health, the Centers for Disease Control, and the FDA, BARDA may share technical deliverables and test results created in the performance of this Contract with colleagues within the PHEMCE as well as within the Department of Health and Human Services (DHHS). This advance understanding does not authorize the Government to share financial information outside of the United States Government. The Contractor is advised to review the terms of FAR 52.227-14 Rights in Data – General, regarding the Government's rights to data produced during the course of performance of this Contract.[1]

g. **Approval of Clinical Protocols**

The Contractor shall submit all clinical protocols and informed consent documents as referenced under this Contract to the COR for review and comment **prior** to seeking other approvals (Institutional Review Board, Human Use Committee, Institutional Animal Care and Use Committee). The Government requires no fewer than ten (10) business days to perform a review. The Contractor shall take this review time into account and submit protocols as early as possible to avoid delays. The Government's comments and feedback shall be addressed prior to approval. The COR will review and provide approval of protocols. Human informed consents shall also be submitted and reviewed with any clinical protocol.

h. **In-Process Review (IPR)**

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.
The Government will provide written or verbal comments, as appropriate, if the Contractor provides a draft prior to a submitting a final presentation.

B.5. 508 COMPLIANCE

The Contractor will be expected to comply with Section 508 requirements on any electronic document

[1] FAR 27.408 permits the Government to obtain less than unlimited rights in data in the event of a cost-sharing contract. A Data Assertions Table has been compiled, and is included as Attachment 4.

submitted to HHS during the period of performance that is intended for public dissemination by either the contractor or HHS or is necessary for proper deployment/use of the product (Clinical Trial protocols, Consent Forms, Investigator's Brochure, etc.).

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

C.1. STATEMENT OF WORK

See Section J – Attachment 1 (Statement of Work) as agreed upon by the Government and Contractor.

C.2 REGULATORY ACTIVITIES

The Contractor shall submit to the COR for review and comment, pre-submission documents, submission documents, results documents, and all proposed regulatory filing documents with the FDA.

C.3 QUALITY

The Contractor may be required to establish and maintain a Quality Management System for the proposed effort with sufficient content to include but not limited to the elements contained in the Code of Federal Regulations Title 21 Part 820.

The Contractor may be required to establish routine internal reviews of the proposed effort with documentation and evidence of the ability to maintain, and adhere to the Code of Federal Regulations Title 21 Part 820.

The Contractor may be required to subcontract for an independent audit of its system quality system adherence, resolve any issues noted by the auditor, and provide the audit findings and resolutions to the Government.

SECTION D – PACKAGING, MARKING, AND SHIPPING

All deliverables required under this Contract shall be packaged, marked and shipped in accordance with Government specifications and Section F. 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 CO, delivery of reports to be furnished to the Government under this Contract (including invoices) shall be delivered to the CO and COR electronically along with a concurrent email notification to the CO and COR (as defined in Section F.3. Electronic Submission) summarizing the electronic delivery.

SECTION E – INSPECTION AND ACCEPTANCE

E.1. FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)

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

FAR Clause	**Title and Date**

FAR 52.246-3, Inspection of Supplies – Cost-Reimbursement (May 2001)
FAR 52.246-5, Inspection of Services – Cost-Reimbursement (April 1984)
FAR 52.246-8, Inspection of Research and Development – Cost Reimbursement (May 2001)
FAR 52.246-9, Inspection of Research and Development (Short Form) (April 1984)
FAR 52.246-16, Responsibility for Supplies (April 1984)

E.2. DESIGNATION OF GOVERNMENT PERSONNEL

For the purpose of this Section E, the designated COR is the authorized representative of the CO. 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.

E.3. INSPECTION, ACCEPTANCE AND CONTRACT MONITORING

Inspection and acceptance of the product, services, and documentation called for herein shall be accomplished by the CO or a duly authorized representative. Delivery, technical inspection and acceptance will be take place at a location designated by the CO or at:

Office of the Assistant Secretary for Preparedness and Response
Biomedical Advanced Research and Development Authority
O'Neill House Office Building
Washington, DC 20515

At the discretion of the Government and independent of activities conducted by the Contractor, with 48 hours notice to the Contractor, the Government reserves the right to conduct site visits and inspections related to this Contract on an as needed basis during normal business hours, including collection of product samples and intermediates held at the location of the Contractor, or its subcontractor. All costs reasonably incurred by the Contractor and subcontractor for such visit and/or inspection shall be allowable costs subject to the Allowable cost requirements in FAR Subpart 31.2. The Contractor shall coordinate these visits and shall have the opportunity to accompany the Government on any such visits. Under time-sensitive or critical situations, the Government reserves the right to suspend the 48 hour notice to the Contractor. The areas included under the site visit could include, but are not limited to: security, regulatory and quality systems, manufacturing processes and cGMP/GLP/GCP compliance related to activities funded under this Contract.

If the Government, Contractor, or other party identifies any issues during an audit, the Contractor shall capture the issues, identify potential solutions, and provide a report to the Government for review and acceptance.

- If issues are identified during the audit, the Contractor shall submit a report to the CO and COR within five (5) business days detailing the finding and corrective action(s) of the audit.
- COR and CO will review the report and provide a response to the Contractor within ten (10) business days.
- Once corrective action is completed, the Contractor will provide a final report to the CO and COR.

SECTION F – DELIVERIES OR PERFORMANCE

F.1. ESTIMATED PERIOD OF PERFORMANCE

The estimated period of performance for this Contract shall be consistent with the dates set forth in the Base Period in Section B.2. If the Government exercises the Option Periods, the period of performance will be extended as described in Section B of the Contract.

F.2. DELIVERABLES

Successful performance of the Contract shall be deemed to occur upon completion of performance of the work set forth in Section J – Attachment 1 (Statement of Work) of the Contract and upon delivery and acceptance, as required by Section J – Attachment 1 (Statement of Work), Section J – Attachment 2 (Deliverables), and Section J – Attachment 3 (Go/No Go Decisions), and of each of the deliverables described in Section C and Section F below, as determined by the COR and CO.

All deliverables and reporting documents listed within this Section shall be delivered electronically to the CO, the Contract Specialist (CS), and the COR as well as in the designated eRoom (the Government's SharePoint site) along with an email unless otherwise specified by the CO.

No.	Deliverable	Deliverable Description	Reporting Procedures and/or Due Dates
01	Kickoff Meeting	The Contractor shall complete a Kickoff meeting after contract award. There will be a teleconference kickoff meeting focused on the contract and a face to face kick-off meeting that will be focused on the technical components of this contract	•Contract kickoff Within 15 days of contract award. •Technical Face to Face kickoff within 3 months. •Contractor shall provide itinerary and agenda at least 2 business days in advance of meeting. •Contractor provides meeting minutes to COR within 5 business days after the meeting. •COR reviews, comments, and approves minutes within 10 business days.
02	Monthly Teleconference	The Contractor shall participate in monthly teleconferences with BARDA to discuss the performance of the contract.	•Contractor provides agenda and slides 24 hrs in advance of the meeting. •Contractor provides meeting minutes to COR within 7 business days of the meeting.
03	Face to Face Project Meetings	The Contractor shall hold Face to Face meetings for program review as designated by the COR. These meetings will be used to discuss contract progress in relation to the program management deliverables described in this contract and SOW as well as study designs, regulatory and manufacturing updates.	• Contractor shall provide itinerary at least 7 days in advance of the meeting. • Contractor shall provide slides 24 hours in advance. • Contractor shall provide meeting minutes 7 days after the meeting.
04	Monthly Technical Progress Reports	Describing project progress over the previous month.	•Monthly Reports shall be submitted on the 15th day of the month after the end of each month. Monthly progress reports are not required for the periods when the Final Report is due. The COR and CO will review the monthly reports with the Contractor and provide feedback. •The Contractor shall provide data and/or specific analysis of data as well as technical report, generated with contract funding as appendices, or as requested.
05	Publications	Any manuscript, scientific meeting abstract, scientific presentation or press release containing data generated under this Contract or referencing the technical work performed under this contract must be submitted to BARDA for review prior to submission	• Contractor must submit all manuscripts or scientific meeting abstracts to COR and CO for review within at least 30 calendar days for manuscripts and 15 calendar days for abstracts.

No.	Deliverable	Deliverable Description	Reporting Procedures and/or Due Dates
			• Contractor must address in writing all concerns raised by BARDA in writing. • Final submissions shall be submitted to BARDA concurrently or no later than one (1) calendar day of its submission.
06	Final Data Submission Package	Contractor must submit a data package consisting of all raw data produced under this contract. Data may be used by the Division of Research, Innovation, and Ventures (DRIVe) for analysis, evaluation, consistent with FAR 52.227-14. This submission package must be delivered in a non-proprietary format. If clinical trial data is included, that data must be provided consistent with applicable privacy laws to protect personally identifiable information (PII).	• Contractor will submit at least 15 days prior to contract end date. Partial data-sets may also be requested for delivery prior to submission of the Final Data Submission Package.
07	Draft Final Report and Final Report	These reports are to include a summation of the work performed and results obtained for the entire Contract period of performance and shall be in sufficient detail to describe comprehensively the results achieved. The reports shall include the following sections: Cover Page, Executive Summary and Results. The Draft Final Report will be submitted to the COR and CO who will review the Draft Final Report and provide the Contractor with comments. The Final Report shall include or address the COR's and CO's written comments on the draft report. Note: There will be one Final Report due at the end of the Base Period and one Final Report encompassing the entire contract due upon completion of the Option Period, if exercised.	• The Contractor shall submit the Draft Final Report to the COR and CO 45 days prior to contract end date, who will review and provide the Contractor with comments. The Final Report shall include or address the COR's and CO's written comments on the draft report. • The Contractor will deliver the final version of the Final Report on or before the completion date of the contract.

a. **Periodic Document Review**

The CO and COR reserve the right to request within the period of performance a non-proprietary technical document for distribution within the Government. Contractor shall provide the technical document within 10 business days of CO or COR request. Contractor can request additional time on an as-needed basis. If edits are recommended, the Contractor must address, in writing, concerns raised by the Government in writing.

b. **Deliverables Arising from FDA Correspondence**

1) FDA Meetings

i. 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 the FDA meetings if requested by BARDA. BARDA may include up to a maximum of four people (COR, CO and up to 2 subject matter experts).

ii. Contractor shall notify BARDA of upcoming FDA meetings within 24 hours of scheduling.

iii. The Contractor shall forward initial Contractor and FDA-issued draft minutes and

final minutes of any meeting with the FDA to the CO and COR within 5 business days of receipt. All documents shall be duly marked as either "Draft" or "Final."

2) FDA Submissions

i. The Contractor shall provide BARDA the opportunity to review and comment upon all documents submitted to the FDA. In addition, an electronic copy of the final FDA submissions will also need to be submitted. All documents shall be duly marked as either "Draft" or "Final."

1. If draft documents are submitted to the COR for review, the COR will provide feedback to Contractor within 10 business days of receipt, or sooner as necessary to address FDA deadlines or requests.

2. If BARDA reviews draft documents, the Contractor shall revise as appropriate their documents to address BARDA's written concerns and/or recommendations prior to FDA submission.

3. Final FDA submissions shall be submitted to the CO and COR concurrently or no later than 5 calendar days of their submission to FDA.

3) FDA Audits

i. In the event of an FDA inspection which occurs as a result of this contract and for the product, or for any other FDA inspection that has the reasonable potential to impact the performance of this contract, the Contractor shall provide the CO and COR with an exact copy (non-redacted) of the FDA Form 483 and the Establishment Inspection Report (EIR) within five (5) business days after the Contractors receipt of those documents. The Contractor shall provide the COR and CO with copies of the plan for addressing areas of non-conformance to FDA regulations for GLP, GMP, or GCP guidelines as identified in the audit report, status updates during the plans execution and a copy of all final responses to the FDA. The Contractor shall also provide redacted copies of any FDA audits received from subcontractors that occur as a result of this contract or for this product. To the extent feasible, the Contractor shall make arrangements for BARDA representative(s) to be present during the final debrief by the regulatory inspector.

ii. If draft documents are submitted to the COR for review, the COR will provide feedback to Contractor within 10 business days of receipt, or sooner as necessary to address FDA deadlines or requests.

iii. If BARDA reviews draft documents, the Contractor shall revise as appropriate their documents to address BARDA's written concerns and/or recommendations prior to FDA submission.

1. Contractor shall notify CO and COR within 10 business days of a scheduled FDA audit or within 24 hours of an ad hoc site visit/audit if the FDA does not provide 10 business days' advance notice.

2. Contractor shall provide copies of any FDA audit report received from subcontractors that occur as a result of this contract or for this product within 5 business days of receiving correspondence from the FDA, Subcontractor, or third party.

3. Within 15 business days of audit report, Contractor shall provide CO with a plan for addressing areas of nonconformance, if any are identified.

Final FDA submissions shall be submitted to the CO and COR.

4) Other FDA Correspondence

The Contractor shall memorialize any critical correspondence between Contractor and FDA as related to activities funded under this contract and submit to BARDA. All such documents shall be duly marked as either "Draft" or "Final." Contractor shall provide such written summary of any FDA correspondence or engagement within 5 business days of correspondence.

c. **Reporting and Meeting Details Specifics**

1) Monthly Progress Report

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

The Contractor shall submit a Monthly Progress Report on or before the 15th calendar day following the last day of each reporting period and shall include the following:

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;

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);

SECTION II Part C: TECHNICAL PROGRESS - For each activity related to the Gantt chart, document the results of work completed. 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. Include progress or status updates for all SOW tasks in each of the monthly technical progress reports for which there is activity ongoing in that SOW task area(s) as well as data for completed studies in any SOW task.

The report shall also 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 reporting period and preprints/reprints of papers and abstracts, and a current/updated Gantt chart;

SECTION II Part E: Outstanding Issues/Anticipated Areas of Concern - a list of any existing contractual concerns that impact the technical scope of work, schedule, or pricing, as well as a list of potential or anticipated areas of concern that may be encountered in the future months. A Monthly Progress Report will not be required in the same month that the Annual or Final Reports are submitted;

2) Final Report(s) Requirement:

This report shall include a summation 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 year of performance plus any fractional part of the initial year. Thereafter, the reporting period shall consist of each calendar year.

The 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;

SECTION I-EXECUTIVE SUMMARY - A brief overview of the work completed and major accomplishments achieved during the reporting period;

SECTION II-PROGRESS

SECTION II Part A: OVERALL PROGRESS - A description of overall progress highlighting the significant accomplishments in the past year;

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;

SECTION II Part C: TECHNICAL PROGRESS - For each activity, document the results of work completed 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. The report should summarize progress made under each SOW task.

3) Monthly Calls

A conference call between the COR and the Contractor’s Project Leaders/delegates and designees shall occur monthly or as directed by the CO and COR. During this call the Contractor’s Project Leaders/delegates and designees will discuss the activities since the last call, any problems that have arisen and the activities planned until the next call takes place. The Contractor’s Project Leaders/delegates may choose to include other key personnel on the conference call to give detailed updates on specific projects as this may be requested by the COR.

4) Project Meetings

The Contractor shall participate in Project Meetings to coordinate the performance of the Contract, as requested by the COR. These meetings may include face-to-face meetings (kick-off meetings, project reviews, etc) with 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 DHHS officials to discuss the technical, regulatory, and ethical aspects of the program. Subject to the data rights provisions in this Contract, the Contractor will provide data, reports, and presentations to groups of outside experts and Government personnel as required by the CO and COR in order to facilitate review of contract activities.

Electronic copies of the conference call meeting minutes/summaries by the Contractor shall be provided via e-mail to the CO and COR by the Contractor within five (5) business days after the

conference call is held. The COR will review these minutes for approval within 15 business days.

d. **Experimental Protocols**

Notwithstanding guidance found under Article H in this document related to clinical protocols, the Contractor shall submit all study/experiment/test plans, designs, and other protocols to BARDA for review and comment before proceeding with a study.

F.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 CO. A final invention statement (see FAR 27.303 (b)(2)(ii)) shall be submitted to the CO prior to the closeout of the Contract.

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 CO at the address listed below.

SECTION G – CONTRACT ADMINISTRATION DATA

G.1. CONTRACTING OFFICER

The following CO will represent the Government for the purpose of this Contract:

Troy Francis
Contracting Officer
HHS/ASPR/AMCG
O'Neill House Office Building
Washington, DC 20515
troy.francis@hhs.gov

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

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

The following COR will represent the Government for the purpose of this contract:

Dr. Kimberly Sciarretta
Contracting Officer's Representative
HHS/ASPR/BARDA
O'Neill House Office Building
Washington, DC 20515
kimberly.sciarretta@hhs.gov

The COR is responsible for:

1) Monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the CO changes in requirements;
2) Assisting the CO 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 Government may unilaterally change its COR designation, after which it will notify Contractor in writing of such change.

G.3. KEY PERSONNEL

Pursuant to the Key Personnel clause incorporated in Section I of this Contract, the following individuals are considered to be essential to the work being performed hereunder:

(b) (6)

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 CO and shall submit comprehensive justification for the diversion or replacement request (including proposed substitutions for key personnel) and qualifications (CV, etc) of the individual proposed as a substitute 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 CO. The Government may modify the contract to add or delete key personnel at the request of the contractor or Government.

G.4. INVOICING

a. Invoices will be submitted each **30 days**. Invoices shall be submitted by the Contractor to the CO with a copy to the COR in accordance with the instructions for completing this form (a sample of which is included as Attachment 4), which accompany the form, in an original and one electronic copy, not later than the 30th day after the close of the reporting period. The line entries for subdivisions of work (CLINs) and elements of cost (expenditure categories), which shall be reported within the total contract, are discussed in paragraph e., below. Subsequent changes and/or additions in the line entries shall be made in writing.

b. Unless otherwise stated in the instructions for completing this form, all columns A through H, shall be completed for each report submitted.

c. The first financial report shall cover the period consisting of the first full three calendar months

following the date of the Contract, in addition to any fractional part of the initial month. Thereafter, reports will be on a quarterly basis.

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

e. The listing of expenditure categories to be reported is incorporated as a part of this Contract and can be found at Attachment 4.

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

g. Contractor invoices/financial reports shall conform to the form, format, and content requirements of the instructions for Attachment 4, and be sent to the following points of contact. Additionally, Contractor may be required to submit to a DRIVe specific invoice tracking system as will be directed by the CO.

CO	COR	PSC
Troy Francis Contracting Officer troy.francis@hhs.gov	Kimberly Sciarretta Contracting Officer's Representative kimberly.sciarretta@hhs.gov	PSC_Invoices@psc.hhs.gov

The Contractor agrees to immediately notify the CO in writing if there is an anticipated overrun (any amount) or unexpended balance (greater than 10%) of the estimated costs for the Base Period (See estimated costs under Section B) and Options, once awarded and the reasons for the variance. These requirements are in addition to the specified requirements of FAR Clause 52.232-20, Limitation of Cost that is incorporated by reference under Section I.1 which states;

Limitation of Cost (Apr 1984)

• The parties estimate that performance of this Contract, exclusive of any fee, will not cost the Government more than (1) the estimated cost specified in the Schedule or, (2) if this is a cost-sharing contract, the Government's share of the estimated cost specified in the Schedule. The Contractor agrees to use its best efforts to perform the work specified in the Schedule and all obligations under this Contract within the estimated cost, which, if this is a cost-sharing contract, includes both the Government's and the Contractor's share of the cost.

• The Contractor shall notify the Contracting Officer in writing whenever it has reason to believe that—

• The costs the Contractor expects to incur under this Contract in the next 60 days, when added to all costs previously incurred, will exceed 75 percent of the estimated cost specified in the Schedule; or

• The total cost for the performance of this Contract, exclusive of any fee, will be either greater or substantially less than had been previously estimated.

• As part of the notification, the Contractor shall provide the Contracting Officer a revised estimate of the total cost of performing this Contract.

• Except as required by other provisions of this Contract, specifically citing and stated to be an exception to this clause—

• The Government is not obligated to reimburse the Contractor for costs incurred in excess of (i) the estimated cost specified in the Schedule or, (ii) if this is a cost-sharing contract, the

estimated cost to the Government specified in the Schedule; and

• The Contractor is not obligated to continue performance under this Contract (including actions under the Termination clause of this Contract) or otherwise incur costs in excess of the estimated cost specified in the Schedule, until the Contracting Officer (i) notifies the Contractor in writing that the estimated cost has been increased and (ii) provides a revise estimated total cost of performing this Contract. If this is a cost-sharing contract, the increase shall be allocated in accordance with the formula specified in the Schedule.

• No notice, communication, or representation in any form other than that specified in paragraph (d)(2) of this clause, or from any person other than the Contracting Officer, shall affect this Contract's estimated cost to the Government. In the absence of the specified notice, the Government is not obligated to reimburse the Contractor for any costs in excess of the estimated cost or, if this is a cost-sharing contract, for any costs in excess of the estimated cost to the Government specified in the Schedule, whether those excess costs were incurred during the course of the Contract or as a result of termination.

• If the estimated cost specified in the Schedule is increased, any costs the Contractor incurs before the increase that are in excess of the previously estimated cost shall be allowable to the same extent as if incurred afterward, unless the Contracting Officer issues a termination or other notice directing that the increase is solely to cover termination or other specified expenses.

• Change orders shall not be considered an authorization to exceed the estimated cost to the Government specified in the Schedule, unless they contain a statement increasing the estimated cost.

• If this Contract is terminated or the estimated cost is not increased, the Government and the Contractor shall negotiate an equitable distribution of all property produced or purchased under the Contract, based upon the share of costs incurred by each.

h. The Contractor shall submit an electronic copy of the payment request to the approving official instead of a paper copy. The payment request shall be transmitted as an attachment via e-mail to the addresses listed above in one of the following formats: MSWord, MS Excel, or Adobe Portable Document Format (PDF). Only one payment request shall be submitted per e-mail and the subject line of the e-mail shall include the Contractor's name, contract number, and unique invoice number.

i. An electronic copy of the payment request shall be uploaded into the designated eRoom and an e-mail notification of the upload will be provided to the CO and COR.

j. All invoice submissions shall be in accordance with FAR Clause 52.232-25 Prompt Payment (Oct 2008).

k. Invoices - Cost and Personnel Reporting, and Variances from the Negotiated Budget.

The Contractor agrees to provide a detailed breakdown on invoices of the following cost categories:

1. Direct Labor - List individuals by name, title/position, hourly/annual rate, level of effort (actual hours or % of effort), and amount claimed
2. Fringe Benefits - Cite rate and amount
3. Overhead - Cite rate and amount
4. Materials & Supplies - Include detailed breakdown when total amount is over $5,000
5. Travel – N/A under this award
6. Consultant Fees - Identify individuals, amounts and activities. Cite appropriate COA
7. Subcontracts - Attach subcontractor invoice(s). Cite appropriate COA

8. Equipment - Cite authorization and amount. Cite appropriate COA
9. Other Direct Costs - Include detailed breakdown when total amount is over $5,000
10. G&A / Indirect Rate - Cite rate and amount (if applicable)
11. Total Cost (illustrating applicable cost-share)

Note: Subcontracts that are cost-reimbursement in nature must also provide similar breakouts in order to enable the Government to review and confirm costs are allocable, allowable, and reasonable.

Additional instructions and an invoice template are provided in Section J – List of Attachments, Invoice/Financing Request Instructions and Contract Financial Reporting Instructions for Cost-Reimbursement Contracts (Attachment 4). All invoices must be signed by a representative of the contractor authorized to certify listed charges are accurate and comply with Government regulations. Invoices shall be signed and submitted electronically.

If applicable, the Contractor shall convert any foreign currency amount(s) in the invoice to U.S. dollars each month, on the 1st of the month, using the foreign exchange rate index published on www.federalreserve.gov. Payment of invoices is subject to the U.S. dollar limits within the Total Costs of CLIN 0001 in Section B of the Contract.

The Government shall use electronic funds transfer to the maximum extent possible when making payments under this Contract. FAR 52.232-33 Payment by Electronic Funds Transfer–System for Award Management, in Section I requires the Contractor to designate in writing a financial institution for receipt of electronic funds transfer payments.

G.5. REIMBURSEMENT OF COST

The Government shall reimburse the Contractor the cost determined by the CO to be allowable (hereinafter referred to as allowable cost) in accordance with FAR Clause 52.216-7, Allowable Cost and Payment incorporated by reference in Section I, Contract Clauses, of this Contract, and FAR Subpart 31.2. Examples of allowable costs include, but are not limited to, the following:

a) All direct materials and supplies that are used in performing 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.

G.6. INDIRECT COST RATES

The following Contractor established provisional billing rates are incorporated into the Contract, and will be utilized for billing purposes during the Base Period (CLIN 0001) and total estimated cost. FAR clause 52.216-7 will be utilized for billing purposes during both the Base Period (CLIN 0001) and total estimated cost.

The following Indirect Cost Ceilings are established for the Base Period (CLIN 0001) and total estimated cost plus Option Periods (CLINs 0002 – 0006) ONLY if exercised by the CO. The Contractor shall not seek reimbursement in excess of the following Indirect Cost Ceilings:

CLIN	Fringe Benefits (b) (4)	Overhead (b) (4)	G&A (b) (4)	Indirect Cost Ceiling
0001	$217,575	$58,476	$363,011	**$639,062**
0002	$62,676	$16,845	$212,527	**$292,048**
0003	$55,698	$14,969	$61,697	**$132,364**
0004	$184,607	$49,615	$241,385	**$475,607**

0005	$582,383	$156,521	$1,104,538	**$1,843,442**
0006	$238,932	$64,216	$269,873	**$573,021**

Use of the above provisional rates does not change any cost ceilings, contract obligations, or specific allowance or disallowance provided for in the Contract.

Final rate proposals must be sent to the CO & cognizant Government auditor, within 6 months subsequent to the fiscal year end. (See also FAR Clause 52.216-7 incorporated herein).

G.7. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

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, an interim evaluation shall be submitted annually.

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 CO. Should Contractor choose to do so, it may challenge that individual's decision in accordance with FAR 52.233-1, incorporated herein by Section I.

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.

Electronic Access to Contractor Performance Evaluations

Contractors that have Internet capability may access evaluations through a secure Web site for review and comment by completing the registration form that can be obtained at the following address:

http://www.cpars.csd.disa.mil/cparsmain.htm

The registration process requires the Contractor to identify an individual that will serve as a primary contact and who will be authorized access to the evaluation for review and comment. In addition, the Contractor will be required to identify an alternate contact that will be responsible for notifying the cognizant contracting official in the event the primary contact is unavailable to process the evaluation within the required 30-day time frame.

G.8. CONTRACT COMMUNICATIONS/CORRESPONDENCE (JULY 1999)

The Contractor shall identify all correspondence, reports, and other data pertinent to this Contract by imprinting the contract number from Page 1 of the Contract.

G.9. GOVERNMENT PROPERTY

In addition to the requirements of the Government Property clause incorporated in Section I of this Contract, the Contractor shall comply with the following:

The Contractor shall submit the report annually, titled "Report of Government Owned, Contractor Held Property" for submitting summary reports required under this Contract, as directed by the CO or his/her designee.

Title will vest in the Government for property purchased as a direct cost. Upon completion of the Contract, disposition of property will be determined by the CO of record pursuant to FAR property regulations.

SECTION H – SPECIAL CONTRACT REQUIREMENTS

H.1 REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

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

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

H.2 PROHIBITION ON CONTRACTOR INVOLVEMENT WITH TERRORIST ACTIVITIES

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

H.3 IDENTIFICATION AND DISPOSITION OF DATA

The Contractor will be required to provide certain data generated under this Contract to DHHS. DHHS reserves the right to review any other data related to performance of this Contract.

The Contractor shall keep copies of all data required by the FDA relevant to this Contract for the time specified by the FDA.

H.4 EXPORT CONTROL NOTIFICATION

Contractors are responsible for ensuring compliance with all export control laws and regulations that may be applicable to the export of and foreign access to their proposed technologies. Contractors may consult with the Department of State with any questions regarding the International Traffic in Arms Regulation (ITAR) (22 C.F.R. Parts 120-130) and /or the Department of Commerce regarding the Export Administration Regulations (15 C.F.R. Parts 730-774).

H.5 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 2.101 and 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 CO promptly that, to the best of its knowledge and belief, no actual or potential conflict of interest exists or to identify to the CO any actual or potential conflict of interest the firm 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 CO. This disclosure shall include a description of actions which the Contractor has taken or proposes to take, after consultation with the CO, to avoid, mitigate, or neutralize the actual or potential conflict of interest. The Contractor shall continue performance until notified by the CO of any contrary action to be taken. Remedies include termination of this Contract for convenience, in whole or in part, if the CO 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 CO, 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.6 INSTITUTIONAL RESPONSIBILITY REGARDING INVESTIGATOR FINANCIAL CONFLICTS OF INTEREST

The Contractor shall comply with the requirements of 45 C.F.R. Part 94, Responsible Prospective Contractors, which promotes objectivity in research by establishing standards to ensure that investigators (defined as the principal investigator and any other person who is responsible for the design, conduct, or reporting of research funded under BARDA contracts) will not be biased by any conflicting financial interest.

As required by 45 C.F.R. Part 94, the Contractor shall, at a minimum:

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

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

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

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

e. Establish adequate enforcement mechanisms and provide for sanctions where appropriate.
If a conflict of interest is identified, the Contractor shall report to the CO, the existence of the conflicting interest found. This report shall be made and the conflicting interest managed, reduced, or eliminated, at least on a temporary basis, within sixty (60) days of that identification.

If the failure of an investigator to comply with the conflict of interest policy has biased the design, conduct, or reporting of the BARDA-funded research, the Contractor must promptly notify the CO of the corrective action taken or to be taken. The CO will take appropriate action or refer the matter to the Contractor for further action, which may include directions to the Contractor on how to maintain appropriate objectivity in the funded research.

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

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

H.7 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.

H.8 DISSEMINATION OF FALSE OR DELIBERATELY MISLEADING INFORMATION

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

H.9 CONFIDENTIALITY OF INFORMATION

a. Confidential information, as used in this article, means information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization.

b. The CO and the Contractor may, by mutual consent, identify elsewhere in this Contract specific information and/or categories of information which the Government will furnish to the Contractor or that the Contractor is expected to generate which is confidential and providing further that the Government is not entitled to unlimited rights to that information pursuant to FAR 52.227-14. Similarly, the Contracting Officer and the Contractor may, by mutual consent, identify such confidential information from time to time during the performance of the contract. Failure to agree will be settled pursuant to the "Disputes" clause.

c. If it is established elsewhere in this Contract that information to be utilized under this Contract, or a portion thereof, is subject to the Privacy Act, the Contractor will follow the rules and procedures of disclosure set forth in the Privacy Act of 1974, 5 U.S.C. 552a, and implementing regulations and policies, with respect to systems of records determined to be subject to the Privacy Act.

d. Confidential information, as defined in paragraph (a) of this article, shall not be disclosed without the prior written consent of the individual, institution, or organization.

e. Whenever the Contractor is uncertain with regard to the proper handling of material under the Contract, or if the material in question is subject to the Privacy Act or is confidential information subject to the provisions of this article, the Contractor should obtain a written determination from the CO prior to any release, disclosure, dissemination, or publication.

f. The provisions of paragraph (d) of this article shall not apply to conflicting or overlapping provisions in other Federal, State or local laws.

H.10 ACCESS TO DOCUMENTATION/DATA

The Government shall have physical and electronic access to all documentation and data generated under this Contract, including: all data documenting Contractor performance; all data generated; all communications and correspondence with regulatory agencies and bodies to include all audit observations, inspection reports, milestone completion documents, and all Offeror commitments and responses. Contractor shall provide the Government with an electronic copy of all correspondence and submissions to the FDA within 5 business days of receipt. The Government shall acquire unlimited rights to all data funded under this contract in accordance with FAR Subpart 27.4 and FAR Clause 52.227-14.

H.11 [Reserved]

H.12 ACKNOWLEDGMENT OF FEDERAL FUNDING

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

activity.

Publication and Publicity

No information related to data obtained under this Contract shall be released or publicized without providing BARDA with at least thirty (30) days advanced notice and an opportunity to review the proposed release or publication.

In addition to the requirements set forth in 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 non-governmental 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. _____."

Press Releases

Misrepresenting contract results or releasing information that is injurious to the integrity of BARDA may be construed as improper conduct. Press releases shall be considered to include the public release of information to any medium, excluding peer-reviewed scientific publications. With the exception of ad-hoc press releases required by applicable law or regulations, the Contractor shall ensure that the COR has received an advance copy of any press release related to the contract not less than two (2) business days prior to the issuance of the press release.

The Contractor shall acknowledge the support of the Department of Health and Human Service, Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

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

a. Contractor Use of the Powered by DRIVe Logo

1) For the limited purposes of the Contractor's participation related to the subject DRIVe contract, Contractor is permitted to use the following logo (the "Logo") for the period of performance of this Contract (or for a longer period, if agreed between the parties), subject to the Contractor's full performance of the terms and conditions of the subject Contract and provided that Contractor shall cease to use the Logo immediately upon BARDA's request.

2) The Contractor's use of the term "Powered by DRIVe" shall be subject to DRIVe Brand Guidelines.

3) Any other use of the DRIVe name, its Logo, servicemarks or trademarks, or any of its other distinguishable marks, whether registered or not, shall be limited to those granted by the express, written permission of the BARDA. Those to whom such permission is granted must agree that BARDA shall remain the final arbiter of the use of the mark or Logo.

b. BARDA Use of Contractor Logo

Contractor hereby grants BARDA/DRIVe the right to use Contractor's corporate logo (and other artwork as agreed to by the parties), for presentations, internal and external websites, and other reasonable promotional and reporting uses relating to the project during the period of performance of the Contract (or for a longer period, if agreed between the parties).

H.13 [Reserved]

H.14 PRIVACY ACT APPLICABILITY

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 C.F.R. Part 5b, Privacy Act Regulations, may be obtained at https://www.gpo.gov/fdsys/granule/CFR-2007- title45-vol1/CFR-2007-title45-vol1-part5b.

The Contractor is responsible for monitoring contractor compliance with the Privacy Act.

The Contractor shall follow the Privacy Act guidance as contained in the Privacy Act System of Records number 09-25-0200.

H.15 LABORATORY LICENSE REQUIREMENTS

The Contractor shall comply with all applicable requirements of Section 353 of the Public Health Service Act (Clinical Laboratory Improvement Act as amended) (42 U.S.C. 263a) and 42 CFR Part 493. This requirement shall also be included in any subcontract for services under the Contract.

H.16 QUALITY ASSURANCE (QA) AUDIT REPORTS

BARDA reserves the right to participate in QA audits as related to activities funded under this Contract. Upon completion of the audit/site visit the Contractor shall provide a report capturing the findings, results and next steps in proceeding with the subcontractor. If action is requested of the subcontractor, detailed concerns for addressing areas of non-conformance to FDA regulations for GLP, GMP, or GCP guidelines, as identified in the audit report, must be provided to BARDA. The Contractor shall provide responses from the subcontractors to address these concerns and plans for corrective action execution.

- Contractor shall notify CO and COR of upcoming, ongoing, or recent audits/site visits of subcontractors as part of weekly communications.

- Contractor shall notify the COR and CO within five (5) business days of report completion.

H.17 BARDA AUDITS

Contractor shall accommodate periodic or reasonable ad hoc site visits during normal business hours by the Government with forty-eight (48) hours advance notice. If the Government, the Contractor, or other parties identifies any issues during an audit, the Contractor shall capture the issues, identify potential solutions, and provide a report to the Government.

- If issues are identified during the audit, Contractor shall submit a report to the CO and COR detailing the finding and corrective action(s) within 10 business days of the audit.
- COR and CO will review the report and provide a response to the Contractor with ten (10) business days.
- Once corrective action is completed, the Contractor will provide a final report to the CO and COR.

H.18 RESTRICTION ON EMPLOYMENT OF UNAUTHORIZED ALIEN WORKERS

The Contractor shall not use Contract funds to employ workers described in Section 274A (h)(3) of the Immigration and National Act, which reads as follows:

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

H.19 NOTIFICATION OF CRITICAL PROGRAMMATIC CONCERNS, RISKS, OR POTENTIAL RISKS

If any action occurs that creates a cause for critical programmatic concern, risk, or potential risk to BARDA or the Contractor an Incident Report shall be delivered to BARDA.

- Within 48 hours of activity or incident or within 24 hours for a security related activity or incident, Contractor must notify BARDA.
- Additional updates due to COR and CO within 48 hours of additional developments.
- Contractor shall submit within 5 business days a Corrective Action Plan (if deemed necessary by either party) to address any potential issues.

If corrective action is deemed necessary, Contractor must address in writing its consideration of concerns raised by BARDA within 5 business days of receiving comments by BARDA.

H.20 [Reserved]

H.21 DISSEMINATION OF INFORMATION (May 2004)

Other than scientific and technical data for which the Contractor can assert a copyright under FAR Clause 52.227-14 (c), no information related to data obtained under this Contract shall be released or publicized without the prior written consent of the CO. In the event that the Contractor seeks to publicize scientific and technical data, the contractor shall provide BARDA, through the COR, with a minimum of thirty (30) business days to review the particular scientific and technical data prior to publication.

H.22 REGISTRATION WITH THE SELECT AGENT PROGRAM FOR WORK INVOLVING THE POSSESSION, USE, AND/OR TRANSFER OF SELECT BIOLOGICAL AGENTS OR TOXINS

Work involving select biological agents or toxins shall not be conducted under this Contract until the

Contractor and any affected subcontractor(s) are granted a certificate of registration or are authorized to work with the applicable select agents.

For prime or subcontract awards to domestic institutions who possess, use, and/or transfer Select Agents under this contract, the institution must complete registration with the Centers for Disease Control and Prevention (CDC), DHHS or the Animal and Plant Health Inspection Services (APHIS), U.S. Department of Agriculture (USDA), as applicable, before performing work involving Select Agents, in accordance with 42 C.F.R. Part 73. No Government funds can be used for work involving Select Agents, as defined in 42 C.F.R. Part 73, if the final registration certificate is denied.

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

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

H.23 MANUFACTURING STANDARDS

The Good Manufacturing Practice Regulations (GMP) (21 C.F.R. Part 820) 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, within the thirty (30) calendar day period, the Contractor fails to take such an action to the satisfaction of the Government Project Officer/COR, or fails to provide a remediation plan that is acceptable to the COR, then the Contract may be terminated.

H.24 LABORATORY LICENSE REQUIREMENTS

The Contractor shall comply with all applicable requirements of 21 C.F.R. Part 58 and FDA Medical Device GMP Guidance. This requirement shall also be included in any subcontract for services under the Contract.

H.25 SHARING RESEARCH DATA

The Contractor's data sharing plan, due date to be determined at contract award, is hereby incorporated by reference. The Contractor agrees to adhere to its plan and shall request prior approval of the Contracting Officer for any changes in its plan.

BARDA endorses the sharing of final research data to serve health. This contract is expected to generate research data that must be shared with the public and other researchers.

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

H.26 PUBLIC ACCESS TO ARCHIVED PUBLICATIONS RESULTING FROM ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE (ASPR) FUNDED RESEARCH

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

H.27 [Reserved]

H.28 [Reserved]

H.29 CLINICAL TERMS OF AWARD

In addition to those terms and conditions outlined under applicable HHSAR clauses incorporated by reference by Section I of this Contract, the following clinical terms of award detail an agreement between the BARDA and the Contractor; they apply to all contracts involving clinical research.

Draft protocols for each clinical study will be submitted to BARDA for evaluation and comment. BARDA comments will be addressed and/or incorporated into the draft protocol prior to submission to the FDA for comment, if required and as appropriate.

BARDA shall have unlimited rights to all protocols, data generated from the execution of these protocols, and final reports, funded by BARDA under this Contract, as defined in Rights in Data Clause in FAR 52.227-14. BARDA reserves the right to request that the Contractor provide any contract deliverable in a non-proprietary form without any restrictive legends to ensure BARDA has the ability to review and distribute the deliverables, as BARDA deems necessary.

Important information regarding performing human subject research is available here and should be addressed by the contractor. https://www.hhs.gov/ohrp/

Any updates to clinical studies (enrollment, technical results, etc) are to be addressed in the Monthly and Annual Progress Reports, as well as technical monthly calls. The Contractor shall advise the COR or designee in writing and via electronic communication in a timely manner of any issues potentially affecting contract performance.

i. Safety and Monitoring Issues

a. Institutional Review Board or Independent Ethics Committee Approval

Before award and then with the annual progress report, the Contractor must submit to BARDA a copy of the current IRB-or IEC-approved informed consent document, documentation of continuing review and approval and the OHRP federal wide assurance number for the institution or site.

If other institutions are involved in the research (e.g., a multicenter clinical trial or study), each

institution's IRB or IEC must review and approve the protocol. They must also provide BARDA initial and annual documentation of continuing review and approval, including the current approved informed consent document and federal wide number.

The Contractor must ensure that the application as well as all protocols are reviewed by their IRB or IEC.

To help ensure the safety of participants enrolled in BARDA-funded studies, the Contractor must provide BARDA copies of documents related to all major changes in the status of ongoing protocols, including the following:

- All amendments or changes to the protocol, identified by protocol version number, date, or both and dates it is valid.
- All changes in informed consent documents, identified by version number, dates, or both and dates it is valid.
- Termination or temporary suspension of patient accrual.
- Termination or temporary suspension of the protocol.
- Any change in IRB approval.
- Any other problems or issues that could affect the participants in the studies.

The Contractor must notify BARDA through the COR or CO of any of the above changes within five (5) working days by email or fax, followed by a letter signed by the institutional business official, detailing notification of the change of status to the local IRB and a copy of any responses from the IRB or IEC.

If a clinical protocol has been reviewed by an institutional biosafety committee (IBC) or the NIH Recombinant DNA Advisory Committee (RAC), the Contractor must provide information about the initial and ongoing review and approval, if any. See the NIH Guidelines for Research Involving Recombinant DNA Molecules.

b. Data and Safety Monitoring Requirements

BARDA strongly recommends independent safety monitoring for clinical trials of investigational drugs, devices, or biologics; clinical trial of licensed products; and clinical research of any type involving more than minimal risk to volunteers. Independent monitoring can take a variety of forms. Phase III clinical trials must be reviewed by an independent data and safety monitoring board (DSMB); other trials may require DSMB oversight as well. The Contractor shall inform BARDA of any upcoming site visits and/or audits of CRO facilities funded under this effort. BARDA reserves the right to accompany the Contractor on site visits and/or audits of CROs as BARDA deems necessary. The Contractor shall inform BARDA 30 days in advance of a DSMB board meetings for studies funded under this effort. BARDA reserves the right to participate in the DSMB board meetings on an impromptu basis as a non-voting member, if feasible per the structure of the study. If not, the communications from the DSMB to the Contractor should be made available to BARDA upon receipt.

A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. For examples, the risk of drawing a small amount of blood from a healthy individual for research purposes is no greater than the risk of doing so as part of a routine physical examination (45 C.F.R. § 46.102(j)).

Final decisions regarding the type of monitoring to be used must be made by the Contractor, based on FDA and BARDA guidance, before enrollment starts. Discussions with the responsible BARDA

PO/CORregarding appropriate safety monitoring must take place, and the Contractor must submit a written response to all concerns raised by BARDA, before patient enrollment begins and may include discussions about the appointment of one of the following:

Independent Safety Monitor – a physician or other appropriate expert who is independent of the study and available in real time to review and recommend appropriate action regarding adverse events and other safety issues.

Independent Monitoring Committee (IMC) or Safety Monitoring Committee (SMC) – a small group of independent investigators and biostatisticians who review data from a particular study.

Data and Safety Monitoring Board – an independent committee charged with reviewing safety and trial progress and providing advice with respect to study continuation, modification, and termination. The Contractor may use an established BARDA DSMB or to organize an independent DSMB. All phase III clinical trials must be reviewed by a DSMB; other trials may require DSMB oversight as well. Please refer to: NIAID Principles for Use of a Data and Safety Monitoring Board (DSMB) For Oversight of Clinical Trials Policy. BARDA should be provided documentation from DSMB and should be provided with any decisions by Contractor regarding the DMSB as it relates to work under this contract.

When a monitor or monitoring board is organized, a description of it, its charter or operating procedures (including a proposed meeting schedule and plan for review of adverse events), and roster and curriculum vitae from all members must be submitted to BARDA before enrollment starts. If concerns are raised, Contractor must address all concerns to BARDA, in writing, before enrollment begins. The Contractor will also ensure that the monitors and board members report any conflicts of interest and the Contractor will maintain a record of this. The Contractor will share conflict of interest reports with BARDA.

Additionally, the Contractor must submit written summaries of all reviews conducted by the monitoring group to the BARDA within thirty (30) days of reviews or meetings.

ii. BARDA Protocol Review Process Before Patient Enrollment Begins

BARDA has a responsibility to ensure that mechanisms and procedures are in place to protect the safety of participants in BARDA-supported clinical trials. Therefore, before patient accrual or participant enrollment, the Contractor must ensure the following (as applicable) are in place at each participating institution, prior to patient accrual or enrollment:

- IRB- or IEC-approved clinical research protocol identified by version number, date, or both, including details of study design, proposed interventions, patient eligibility, and exclusion criteria.
- Documentation of IRB or IEC approval, including OHRP federal wide number, IRB or IEC registration number, and IRB and IEC name.
- IRB- or IEC- approved informed consent form/document, identified by version number, date, or both and dates it is valid.
- Plans for the management of side effects.
- Procedures for assessing and reporting adverse events.
- Plans for data and safety monitoring (see above) and monitoring of the clinical study site, pharmacy, and laboratory.
- Documentation that the Contractor and all study staff responsible for the design or conduct of the research have received training in the protection of human subjects.

Documentation to demonstrate that each of the above items are in place shall be submitted to BARDA) for evaluation and comment in conjunction with the protocol. Execution of clinical studies requires written authorization from BARDA in accordance with this section of this contract.

iii. Investigational New Drug or Investigational Device Exemption Requirements

Consistent with federal regulations, applicable clinical research projects involving the use of investigational therapeutics, vaccines, or other medical interventions (including licensed products and devices for a purpose other than that for which they were licensed) in humans under a research protocol must be performed under a FDA investigational new drug (IND) or investigational device exemption (IDE).

Where an IND and IDE is otherwise required, exceptions must be granted in writing by FDA. If the proposed clinical trial will be performed under an IND or IDE, the Contractor must provide BARDA with the name and institution of the IND or IDE sponsor, the date the IND or IDE was filed with FDA, the FDA IND or IDE number, any written comments from FDA, and the written responses to those comments.

In instances in which an IND or IDE is required, unless FDA notifies Contractor otherwise, the Contractor must wait thirty (30) calendar days from FDA receipt of an initial IND or IDE application before initiating a clinical trial.

The Contractor must notify BARDA if the FDA places the study on clinical hold and provide BARDA any written comments from FDA, written responses to the comments, and documentation in writing that the hold has been lifted.

The Contractor must not use grant or contract funds during a clinical hold to fund clinical studies that are on hold other than costs that are associated with activities related to patients coming off study, monitoring, or ending the study. The Contractor must not enter into any new financial obligations related to clinical activities for the clinical trial on clinical hold.

iv. Required Time-Sensitive Notification

a. Under an IND or IDE, the sponsor must provide FDA safety reports of serious adverse events. Under these Clinical Terms of Award, the Contractor must submit copies to the responsible BARDA representative or the COR as follows:

- Expedited safety report of unexpected or life-threatening experience or death. A copy of any report of unexpected or life-threatening experience or death associated with the use of an IND drug, which must be reported to FDA by telephone or fax as soon as possible but no later than seven (7) days after the IND sponsor's receipt of the information, must be submitted to BARDA representative or COR within 24 hours of FDA notification.

- Expedited safety reports of serious and unexpected adverse experiences. A copy of any report of unexpected and serious adverse experience associated with use of an IND drug or any finding from tests in laboratory animals that suggests a significant risk for human subjects, which must be reported in writing to FDA as soon as possible but no later than 15 days after the IND sponsor's receipt of the information, must be submitted to the BARDA representative or COR within 24 hours of FDA notification.

- IDE reports of unanticipated adverse device effect. A copy of any reports of unanticipated adverse device effect submitted to FDA must be submitted to BARDA representative or COR within 24 hours of FDA notification.

- Expedited safety reports. Sent to BARDA representative or the COR concurrently with the report to FDA.

- Other adverse events documented during the course of the trial should be included in the annual IND or IDE report and reported to BARDA annually.

b. Safety reporting for research not performed under an IND or IDE:

Final decisions regarding ongoing safety reporting requirements for research not performed under an IND or IDE must be made jointly by the BARDA PO or the COR and the

Contractor.

In case of problems or issues the COR will contact the Contractor within ten (10) working days by email or fax, followed within thirty (30) calendar days by an official letter to the Contractor's Project Manager, with a copy to the institutions' office of sponsored programs, listing issues and appropriate actions to be discussed.

c. Human Material (Assurance of OHRP Compliance).

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

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

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

H.29. FOREIGN TRANSFER OF ASSETS OR TECHNOLOGY

This clause shall remain in effect during the term of the Contract and for five (5) years thereafter.

a. Definitions

AFFILIATES: Associated business concerns, non-profit organizations, or individuals if, directly or indirectly, (1) either one controls or can control the other; or (2) a third party controls or can control both.
ASSET(S): Tangible or intangible manifestations of technologies having economic value and capable of being conveyed between economic or Governmental entities that is the focus/scope of development by the U.S. Government ("USG") and Contactor in this Contract.

ASSET(S): Tangible or intangible manifestations of technologies having economic value and capable of being conveyed between economic or Governmental entities that is the focus/scope of development by the U.S. Government (the "USG") and Contactor in this Contract.

FOREIGN FIRM OR INSTITUTION: A firm or institution organized or existing under the laws of a country other than the United States of America (U.S.), its territories, or possessions. The term includes, for purposes of this Contract, any agency or instrumentality of a foreign government; and firms, institutions or business organizations which are owned or substantially controlled by foreign governments, firms, institutions, or individuals.

TECHNOLOGY: Technical Data, Computer Software, manufactured materials and Subject Inventions funded by the USG under this Contract. Technology also includes contractor *know how*

and personnel expertise, as well as other Assets necessary to assure successful completion of this Contract.

U.S. FIRM OR INSTITUTION: A firm or institution organized or existing under the laws of the United States, its territories, or possessions. The term includes, for purposes of this Contract, any agency or instrumentality of the USG; and firms, institutions or business organizations which are owned or substantially controlled by U.S. citizens, firms, institutions, governmental agencies or individuals.

b. General

The parties agree that research findings and technological developments made under this Contract constitute an investment by the USG on behalf of its citizens in the interest of their economic and national health security. These investments are made for the primary benefit of the citizenry of the United States with those same benefits potentially accruing to the people of all nations. Therefore, the USG has a fiduciary responsibility to protect the full invested value of the Assets and Technology developed under this Contract. The USG is also cognizant of the duty the Contractor has to its shareholders and other stakeholders with a vested interested in the economic success of the Contractor. At times both parties are aware their respective interests may diverge. Therefore, in the course of conducting business though the Contract, access to technology developments under this Contract by Foreign Firms or Institutions must be carefully considered.

c. Export Controls

Contractor agrees to comply with all applicable laws regarding export controls and not to export any Asset or Technology to any U.S. embargoed countries.

d. Post-award Transfer of Ownership of Assets or Technology

The Contractor shall provide notice to the Contracting Officer and COR within three (3) business days of any discussions of a proposed transfer of ownership or establishment of a licensing agreement of any Asset or Technology funded under this Contract from the Contractor to a Foreign Firm or Institution. Notice will also be given within three (3) business days of any discussions of a proposed transfer of operational, corporate, or economic control of Assets and Technology funded under this Contract to Foreign Firms or Institutions. This Article shall not apply to transfers by the Contractor to Affiliated entities of the Contractor, as well as technology transfers for the purposes of manufacturing in accordance with the Statement of Work.

Prior to transferring any Asset funded by the USG under this Contract, the Contractor should carefully review the USG rights under FAR Subpart 42.12 pertaining to Novation, specifically FAR section 42.1204. That provision provides that the USG may recognize a third party assignment only if the transfer of Assets and Technology is determined to be in the USG's interests. The Contractor should be aware that the USG is under **no** obligation to recognize a successor in interest. If the Contracting Officer determines that a transfer of Assets and Technology may have adverse consequences to the economic well-being or national health security interests of the U.S., the Contractor, and the Contracting Officer shall jointly endeavor to find alternatives to the proposed transfer which obviate or mitigate potential adverse consequences of the transfer but which may provide substantially equivalent benefits to the Contractor.

In addition to the USG licensing rights to subject inventions and technical data funded under this Contract, see FAR clause 52.227-11 (Patent Rights-Ownership by the Contractor) and FAR Clause 52.227-14 (Rights in Data - General), the USG shall have a first right of refusal for the purchase of the Asset and/or Technology funded under the Contract. The USG may waive this first right of refusal in writing submitted to the Contractor within ninety (90) calendar days of the initial notification to the USG of the Contractor's intent to conduct any form of Asset or corporate transfer.

Except for transfers to affiliates of the Contractor, including those entities necessary to complete the Statement of Work, the Contractor shall provide written notice to the CO and COR of the scheduled transfer to a Foreign Firm or Institution at least ninety (90) calendar days prior to the scheduled date

of transfer. Such notice shall cite this Article and shall specifically identify the Asset or Technology proposed for the transfer and the general terms of the transfer. **No transfer shall take place without written concurrence from the Contracting Officer.**

e. Transfer to a Prohibited Source

In the event of a transfer of an Asset and/or Technology by the Contractor to a Foreign Firm or Institution which is identified as a Prohibited Source pursuant to FAR Subpart 25.7: (a) the USG may terminate this Contract for cause and (b) the license rights to the technical data and subject invention under the relevant FAR IP Clauses (FAR Clause 52.227-11 and FAR Clause 52-227-14) shall survive the termination. Upon request of the USG, the Contractor shall provide written confirmation of such licenses.

a. Lower Tier Agreements

The Contractor shall include this Article, suitably modified, to identify the Parties, in all subcontracts or lower tier agreements, regardless of tier.

PART II - CONTRACT CLAUSES

SECTION I – CONTRACT CLAUSES

I.1. FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)

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

General Clauses for Cost-Sharing Research and Development (R&D) Contract

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

Reg	Clause	Date	Clause Title
FAR	52.202-1	Nov 2013	Definitions
FAR	52.203-3	Apr 1984	Gratuities
FAR	52.203-5	May 2014	Covenant Against Contingent Fees
FAR	52.203-6	Sep 2006	Restrictions on Subcontractor Sales to the Government
FAR	52.203-7	May 2014	Anti-Kickback Procedures
FAR	52.203-8	May 2014	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity
FAR	52.203-10	May 2014	Price or Fee Adjustment for Illegal or Improper Activity
FAR	52.203-11	Sept 2007	Certification and Disclosure Regarding Payments to Influence Certain Federal Transactions
FAR	52.203-12	Oct 2010	Limitation on Payments to Influence Certain Federal Transactions
FAR	52.203-13	Oct 2015	Contractor Code of Business Ethics and Conduct
FAR	52.203-14	Oct 2015	Display of Hotline Poster(s)
FAR	52.203-17	Apr 2014	Contractor Employee Whistleblower Rights and Requirement To Inform Employees of Whistleblower Rights
FAR	52.203-19	Jan 2017	Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements
FAR	52.204-1	Dec 1989	Administrative Matters Provisions and Clauses
FAR	52.204-4	May 2011	Printed or Copied Double-Sided on Postconsumer Fiber Content Paper
FAR	52.204-7	Oct 2018	System for Award Management
FAR	52.204-10	Oct 2018	Reporting Executive Compensation and First-Tier Subcontract Awards
FAR	52.204-13	Oct 2018	System for Award Management Maintenance
FAR	52.204-18	Jul 2015	Commercial and Government Entity Code Maintenance
FAR	52.204-23	Jul 2018	Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities
FAR	52.204-25	Aug 2019	Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment.
FAR	52.207-1	May 2006	Notice of Standard Competition
FAR	52.209-6	Oct 2015	Protecting the Government's Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment
FAR	52.209-9	Jul 2013	Updates of Publicly Available Information Regarding Responsibility Matters

FAR	52.209-10	Nov 2015	Prohibition on Contracting with Inverted Domestic Corporations
FAR	52.210-1	Apr 2011	Market Research
FAR	52.211-5	Aug 2000	Material Requirements
FAR	52.215-2	Oct 2010	Audit and Records – Negotiation
FAR	52.215-8	Oct 1997	Order of Precedence - Uniform Contract Format
FAR	52.215-10	Aug 2011	Price Reduction for Defective Cost or Pricing Data
FAR	52.215-11	Aug 2011	Price Reduction for Defective Certified Cost or Pricing Data —Modifications.
FAR	52.215-12	Oct 2010	Subcontractor Certified Cost or Pricing Data
FAR	52.215-13	Oct 2010	Subcontractor Certified Cost or Pricing Data—Modifications
FAR	52.215-14	Oct 2010	Integrity of Unit Prices (Over the Simplified Acquisition Threshold
FAR	52.215-15	Oct 2010	Pension Adjustments and Asset Reversions
FAR	52.215-18	Jul 2005	Reversion or Adjustment of Plans for Postretirement Benefits (PRB) other than Pensions
FAR	52.215-19	Oct 1997	Notification of Ownership Changes
FAR	52.215-20	Oct 2010	Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data
FAR	52.215-21	Oct 2010	Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data – Modifications
FAR	52.215-22	Oct 2009	Limitations on Pass-Through Charges—Identification of Subcontract Effort
FAR	52.215-23	Oct 2009	Limitations on Pass-Through Charges
FAR	52.216-7	Jun 2013	Allowable Cost and Payment
FAR	52.216-12	Apr 1988	Cost Sharing Contract
FAR	52/217-9	Mar 2000	Option to Extend the Term of the Contract
FAR	52.219-8	Oct 2014	Utilization of Small Business Concerns
FAR	52.219-16	Jan 1999	Liquidated Damages - Subcontracting Plan
FAR	52.219-28	Jul 2013	Post-Award Small Business Program Representation
FAR	52.222-3	Jun 2003	Convict Labor
FAR	52.222-21	Apr 2015	Prohibition of Segregated Facilities
FAR	52.222-24	Feb 1999	Pre-award On-Site Equal Opportunity Compliance Evaluation
FAR	52.222-25	Apr 1984	Affirmative Action Compliance
FAR	52.222-26	Sept 2016	Equal Opportunity
FAR	52.222-35	Oct 2015	Equal Opportunity for Veterans ($150,000 or more)
FAR	52.222-36	Jul 2014	Equal Opportunity for Workers with Disabilities
FAR	52.222-37	Feb 2016	Employment Reports on Veterans
FAR	52.222-38	Feb 2016	Compliance with Veterans' Employment Reporting Requirements
FAR	52.222-40	Dec 2010	Notification of Employee Rights Under the National Labor Relations Act
FAR	52.222-50	Mar 2015	Combating Trafficking in Persons
FAR	52.222-54	Oct 2015	Employment Eligibility Verification
FAR	52.222-62	Jan 2017	Paid Sick Leave Under Executive Order 13706
FAR	52.223-6	May 2001	Drug-Free Workplace
FAR	52.223-18	Aug 2011	Encouraging Contractor Policy to Ban Text Messaging While Driving
FAR	52.225-13	Jun 2008	Restrictions on Certain Foreign Purchases
FAR	52.225-25	Oct 2015	Prohibition on Contracting with Entities Engaging in Certain Activities or Transactions Relating to Iran—Representation and

			Certifications
FAR	52.226-1	Jun 2000	Utilization of Indian Organizations and Indian-Owned Economic Enterprises.
FAR	52.227-1	Dec 2007	Authorization and Consent, Alternate 1 (APR 1984)
FAR	52.227-2	Dec 2007	Notice and Assistance Regarding Patent and Copyright Infringement
FAR	52.227-3	Apr 1984	Patent Indemnity
FAR	52.227-11	May 2014	Patent Rights – Ownership by the Contractor
FAR	52.227-14	May 2014	Rights in Data – General
FAR	52.227-15	Dec 2007	Representation of Limited Rights Data and Restricted Computer Software
FAR	52.227-16	June 1987	Additional Data Requirements
FAR	52.228-7	Mar 1996	Insurance – Liability to Third Persons
FAR	52.230-2	Oct 2015	Cost Accounting Standards
FAR	52.230-3	Oct 2015	Disclosure and Consistency of Cost Accounting Practices
FAR	52.230-6	Jun 2010	Administration of Cost Accounting Standards
FAR	52.232-9	Apr 1984	Limitation on Withholding of Payments
FAR	52.232-17	May 2014	Interest
FAR	52.232-20	Apr 1984	Limitation of Cost
FAR	52.232-23	May 2014	Assignment of Claims
FAR	52.232-25	Jan 2017	Prompt Payment
FAR	52.232-33	Jul 2013	Payment by Electronic Funds Transfer–System for Award Management
FAR	52.232.39	Jun 2013	Unenforceability of Unauthorized Obligations
FAR	52.232-40	Dec 2013	Providing Accelerated Payments to Small Business Subcontractors
FAR	52.233-1	May 2014	Disputes
FAR	52.233-3	Aug 1996	Protest After Award, Alternate 1 (Jun 1985)
FAR	52.233-4	Oct 2004	Applicable Law for Breach of Contract Claim
FAR	52.242-1	Apr 1984	Notice of Intent to Disallow Costs
FAR	52.242-3	May 2014	Penalties for Unallowable Costs
FAR	52.242-4	Jan 1997	Certification of Final Indirect Costs
FAR	52.242-13	Jul 1995	Bankruptcy
FAR	52.242-15	Aug 1989	Stop Work Order
FAR	52.242-15 Alt. I	Aug 1989	Stop Work Order
FAR	52.243-2	Aug 1987	Changes – Cost-Reimbursement Alternate V (Apr 1984)
FAR	52.244-2	Oct 2010	Subcontracts, Alternate 1 (Jun 2007)
FAR	52.244-5	Dec 1996	Competition in Subcontracting
FAR	52.244-6	Jan 2019	Subcontracts for Commercial Items
FAR	52.245-1	Jan 2017	Government Property
FAR	52.245-9	Apr 2012	Use and Charges
FAR	52.246-23	Feb 1997	Limitation of Liability
FAR	52.249-6	May 2004	Termination (Cost-Reimbursement)
FAR	52.249-14	Apr 1984	Excusable Delays
FAR	52.253-1	Jan 1991	Computer Generated Forms

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION

REGULATION (HHSAR) (48 CFR CHAPTER 3) CLAUSES:

Reg	Clause	Date	Clause Title
HHSAR	352.203-70	Dec 2015	Anti-Lobbying
HHSAR	352.208-70	Dec 2015	Printing and Duplication
HHSAR	352.211-3	Dec 2015	Paperwork Reduction Act
HHSAR	352.219-70	Dec 2015	Mentor-Protégé Program
HHSAR	352.219-71	Dec 2015	Mentor-Protégé Program Reporting Requirements
HHSAR	352.222-70	Dec 2015	Contractor Cooperation in Equal Employment Opportunity Investigations
HHSAR	352.223-70	Dec 2015	Safety and Health
HHSAR	352.224-70	Dec 2015	Privacy Act
HHSAR	352.224-71	Dec 2016	Confidential Information
HHSAR	352.227-70	Dec 2015	Publications and Publicity
HHSAR	352.231-70	Dec 2015	Salary Rate Limitation (included in full text below)
HHSAR	352.233-71	Dec 2015	Litigation and Claims
HHSAR	352.237-75	Dec 2015	Key Personnel
HHSAR	352.239-74	Dec 2015	Electronic and Information Technology Accessibility
HHSAR	352.270-6	Dec 2015	Restriction on Use of Human Subjects.
HHSAR	352.270-9	Dec 2015	Non-discrimination for Conscience
HHSAR	352.270-13	Dec 2015	Continued Ban on Funding Abortion and Continued Ban on Funding of Human Embryo Research.

I.2. ADDITIONAL FAR CONTRACT CLAUSES INCLUDED IN FULL TEXT

This contract incorporates the following clauses in full text. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES:

FAR Clause 52.217-8 Option to Extend Services (Nov 1999)

The Government may require continued performance of any services within the limits and at the rates specified in the contract. These rates may be adjusted only as a result of revisions to prevailing labor rates provided by the Secretary of Labor. The option provision may be exercised more than once, but the total extension of performance hereunder shall not exceed 6 months. The Contracting Officer may exercise the option by written notice to the Contractor within 5 days of end of period of performance.

FAR Clause 52.219-28, Post-Award Small Business Program Representation (July 2013)

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

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

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

sales territory, and nature of business activity.

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

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

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

(3) For long-term contracts--

(i) Within 60 to 120 days prior to the end of the fifth year of the contract; and
(ii) Within 60 to 120 days prior to the date specified in the contract for exercising any option thereafter.

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

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

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

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

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

The Contractor represents that it [ ] is, **[X] is not** a small business concern under NAICS Code 541715 assigned to this contract.

FAR 52.204-21 Basic Safeguarding of Covered Contractor Information Systems (Jun 2016)

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

“Covered contractor information system” means an information system that is owned or operated by a contractor that processes, stores, or transmits Federal contract information.

“Federal contract information” means information, not intended for public release, that is provided by or generated for the Government under a contract to develop or deliver a product or service to the Government, but not including information provided by the Government to the public (such as on public Web sites) or simple transactional information, such as necessary to process payments.

“Information” means any communication or representation of knowledge such as facts, data, or opinions, in any medium or form, including textual, numerical, graphic, cartographic, narrative, or audiovisual (Committee on National Security Systems Instruction (CNSSI) 4009).

“Information system” means a discrete set of information resources organized for the collection, processing, maintenance, use, sharing, dissemination, or disposition of information (44 U.S.C. 3502).

“Safeguarding” means measures or controls that are prescribed to protect information systems.

(b) Safeguarding requirements and procedures.

(1) The Contractor shall apply the following basic safeguarding requirements and procedures to protect covered contractor information systems. Requirements and procedures for basic safeguarding of covered contractor information systems shall include, at a minimum, the following security controls:

(i) Limit information system access to authorized users, processes acting on behalf of authorized users, or devices (including other information systems).
(ii) Limit information system access to the types of transactions and functions that authorized users are permitted to execute.
(iii) Verify and control/limit connections to and use of external information systems.
(iv) Control information posted or processed on publicly accessible information systems.
(v) Identify information system users, processes acting on behalf of users, or devices.
(vi) Authenticate (or verify) the identities of those users, processes, or devices, as a prerequisite to allowing access to organizational information systems.
(vii) Sanitize or destroy information system media containing Federal Contract Information before disposal or release for reuse.
(viii) Limit physical access to organizational information systems, equipment, and the respective operating environments to authorized individuals.
(ix) Escort visitors and monitor visitor activity; maintain audit logs of physical access; and control and manage physical access devices.
(x) Monitor, control, and protect organizational communications (i.e., information transmitted or received by organizational information systems) at the external boundaries and key internal boundaries of the information systems.
(xi) Implement subnetworks for publicly accessible system components that are physically or logically separated from internal networks.
(xii) Identify, report, and correct information and information system flaws in a timely manner.
(xiii) Provide protection from malicious code at appropriate locations within organizational information systems.
(xiv) Update malicious code protection mechanisms when new releases are available.
(xv) Perform periodic scans of the information system and real-time scans of files from external sources as files are downloaded, opened, or executed.

(2) *Other requirements*. This clause does not relieve the Contractor of any other specific safeguarding requirements specified by Federal agencies and departments relating to covered contractor information systems generally or other Federal safeguarding requirements for controlled unclassified information (CUI) as established by Executive Order 13556.

(c) *Subcontracts*. The Contractor shall include the substance of this clause, including this paragraph (c), in subcontracts under this contract (including subcontracts for the acquisition of commercial items, other than commercially available off-the-shelf items), in which the subcontractor may have Federal contract information residing in or transiting through its information system.

(End of clause)

I.2. ADDITIONAL HHSAR CONTRACT CLAUSES INCLUDED IN FULL TEXT

HHSAR 352.231-70 – Salary Rate Limitation (December 18, 2015)

i. Pursuant to the current and applicable prior HHS appropriations acts, payment of the direct salary of an individual at a rate in excess of the Federal Executive Schedule Level II in effect on the date Government funding was obligated.

ii. For purposes of the salary rate limitation, the terms "direct salary," "salary", and "institutional base salary", have the same meaning and are collectively referred to as "direct salary", in this clause. An individual's direct salary is the annual compensation that the Recipient pays for an individual's direct effort (costs) under the contract. Direct salary excludes any income that an individual may be permitted to earn outside of duties to the Recipient. Direct salary also excludes fringe benefits, overhead, and general and administrative expenses (also referred to as indirect costs or facilities and administrative [F&A] costs).

Note: The salary rate limitation does not restrict the salary that an organization may pay an individual working under a Government contract, order, or OTAR; it merely limits the portion of that salary that may be paid with Federal funds.

iii. The salary rate limitation also applies to individuals under Sub-Recipient Agreements except to the extent that that a Sub-Recipient Agreement is awarded on a fixed-price basis without analysis of labor costs. If this is a multiple-year contract, it may be subject to unilateral modification by the CO to ensure that an individual is not paid at a rate that exceeds the salary rate limitation provision established in the HHS appropriations act in effect when the expense is incurred regardless of the rate initially used to establish Agreement funding.

iv. See the salaries and wages pay tables on the U.S. Office of Personnel Management Web site for Federal Executive Schedule salary levels that apply to the current and prior periods

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

The following documents are attached and incorporated in this contract:

1. Statement of Work, dated 27 Sept 2019
2. Deliverables Table
3. Go/No Go/No Go Milestones & Decision Gating
4. Data Assertion Table
5. Sample Invoice/Financial Request Instructions and Contract Financial Reporting Instructions for BARDA Cost-Sharing Contracts
6. Report of Government Owned, Contractor Held Property

   Located at: https://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/Govt- Owned-Prop.pdf
7. Final Technical Proposal submission dated 27 Sept 2019 is incorporated by reference.
8. Final Cost Proposal submission dated 27 Sept 2019 is incorporated by reference.

PART IV - REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

The following documents are incorporated by reference in this contract:

1) Human Subjects Assurance Identification Numbers: To be provided prior to study execution for each subcontractor and/or clinical site

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

End of Contract

Attachment 1 – Statement of Work

Independently, and not as an agent of the Government, the Contractor shall furnish all necessary services, qualified professional, technical, and administrative personnel, material, equipment and facilities, not otherwise provided by the Government under the terms of this contract, as needed to perform the tasks set forth below.

Statement of Work

Monocyte Distribution Width (MDW) and Predictive Analytic Algorithms for Sepsis Detection Area of Interest Number (BARDA BAA-18-100-SOL-00003; Research Area of Interest 15.1: Advanced Research and Development of Sepsis Diagnostics and Devices)

1. PREAMBLE

Independently, and not as an agent of the government, the contractor shall furnish all necessary services; qualified professional, technical, and administrative personnel; and material, equipment, and facilities not otherwise provided by the government under the terms of this contract, as needed to perform the tasks set forth below.

2. OVERALL OBJECTIVES AND SCOPE

The overall objective of this contract is to develop and commercialize a solution for the accurate detection and prediction of sepsis. The scope of work for this contract includes identifying a set of hematology instrument parameters for accurately detecting and predicting sepsis, training and validating a machine learning algorithm which incorporates additional data from medical records to detect and predict sepsis onset up to several days earlier than the current state of the art, and commercializing the solution which incorporates the algorithm as part of a Software as a Medical Device (SaMD) cleared by the FDA.

The effort for "Monocyte Distribution Width (MDW) and Predictive Analytic Algorithms for Sepsis Detection" will progress in phases that cover the base performance segment to be labeled Contract Line Item Number (CLIN) 0001, followed by optional phases. The scope of work is broken into 6 CLINs, which are discrete work segments:

1. CLIN0001 – (b) (4)
2. CLIN0002 – (b) (4)
3. CLIN0003 – (b) (4)
4. CLIN0004 – (b) (4)
5. CLIN0005 – (b) (4)
6. CLIN0006 – (b) (4)

Contractor will provide program management to ensure timely execution of the tasks defined for the CLINs. Program management scope in base phase (CLIN 0001) is consistent with program management scope in each option phase.

(b) (4)

(b) (4)

Figure 1. Beckman Sepsis Solution

(b) (4)

(b) (4)

(b) (4)		
		increase the

		(b) (4)	

CLIN0001 –(b) (4)

1.0. Program management.

(b) (4)

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(b) (4)

Attachment 1 – Statement of Work

(b) (4)

Attachment 1 – Statement of Work

(b) (4)

Attachment 1 – Statement of Work

(b) (4)

(b) (4)

(b) (4)

CLIN0002 – (b) (4)

2.0. Program management.

Contractor will provide program management to ensure timely execution of the tasks defined for this CLIN. Program management scope in base phase (CLIN 0001) is consistent with program management scope in each option phase.

(b) (4)

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(b) (4)

CLIN0003 – (b) (4)

3.0. Program management

Contractor will provide program management to ensure timely execution of the tasks defined for this CLIN. Program management scope in base phase (CLIN 0001) is consistent with program management scope in each option phase.

(b) (4)

CLIN0004 – (b) (4)

4.0. Program management.

Contractor will provide program management to ensure timely execution of the tasks defined for this CLIN. Program management scope in base phase (CLIN 0001) is consistent with program management scope in each option phase.

(b) (4)

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(b) (4)

CLIN0005 –(b) (4)

5.0. Program management.

Contractor will provide program management to ensure timely execution of the tasks defined for this CLIN. Program management scope in base phase (CLIN 0001) is consistent with program management scope in each option phase.

CLIN0006 – (b) (4)

6.0. Program management.

Contractor will provide program management to ensure timely execution of the tasks defined for this CLIN. Program management scope in base phase (CLIN 0001) is consistent with program management scope in each option phase.

3. PROGRAM MANAGEMENT

Contractor will provide the following as outlined below and in the contract deliverables list

3.1. The overall management, integration, and coordination of all contract activities, including a technical and administrative infrastructure to ensure the efficient planning, initiation, implementation, and direction of all contract activities;

3.2. A principal investigator (PI) responsible for project management, communication, tracking, monitoring, and reporting on status, progress, and modification to the project requirements and timelines, including projects undertaken by subcontractors.

3.3. A project manager (PM) with responsibility for monitoring and tracking day-today progress and timelines; coordinating communication and project activities; costs incurred; and program management.

3.4. A BARDA liaison with responsibility for effective communication with the Contracting Officer (CO) and Contracting Officer's Representative (COR).

3.5. Administrative and legal staff with responsibility for developing compliant subcontracts, consulting, and other legal agreements; ensuring timely acquisition of all proprietary rights, including intellectual property (IP) rights; and reporting all inventions made in the performance of the contract;

3.6. Administrative staff with responsibility for financial management and reporting on all activities conducted by the contractor and any subcontractors;

3.7. Contract review meetings. Contractor will participate in regular meetings to coordinate and oversee the contract effort conjointly with the CO and COR. Contractor will participate in teleconferences monthly with the CO and COR to discuss the performance of

the contract and provide updates on SOW tasks, deliverables, go/no go milestones and Gantt chart.

3.7.1. Go/No-Go Milestones: "Go/No-Go" milestone criteria (entrance and exit criteria for each phase of the project). Milestone Reporting: Upon completion of a stage of the product development, as defined in the agreed upon Go/no Go milestone chart, the contractor shall prepare and submit to the CO and COR a Report that contains
(i) sufficient detail, documentation, and analysis to support successful completion of the stage according to the predetermined qualitative and quantitative criteria that were established for Go/No-Go milestone; and
(ii) a description of the next stage of product development to be initiated and a request for approval to proceed to the next stage of product development.

3.7.2. Project Management Plan: Contractor will utilize Project Progress Management tools/techniques to track and monitor the cost and schedule of the project.

3.8. Risk Management Plan: Contractor will develop a risk management plan highlighting potential problems and/or issues that may arise during the life of the contract; their impact on cost, schedule, and performance; and appropriate remediation plans.

3.9. Project Status Reports. Contractor will deliver project status reports to the CO on a quarterly basis.

3.10. Data Management: Contractor will develop and implement data management and quality control systems/procedures, including transmission, storage, confidentiality, and retrieval of all contract data.

[End of Document]

Attachment 2 – Deliverables Table

Deliverables Table: A detailed description of the results and products to be delivered

Contract Period	WBS Element	Milestone	Deliverable	Success Criteria	Estimated Completion Date
CLIN0001	[redacted]	[redacted]	[redacted] [redacted]	[redacted]	[redacted]
CLIN0001	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
CLIN0001	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Attachment 2 – Deliverables Table

Contract Period	WBS Element	Milestone	Deliverable	Success Criteria	Estimated Completion Date
CLIN0001	(b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4) (b) (4)(b) (4) (b) (4)	(b) (4)(b) (4) (b) (4) (b) (4)	(b) (4)(b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4)(b) (4)	(b) (4)(b) (4) (b) (4)(b) (4)(b) (4) (b) (4)(b) (4) (b) (4)(b) (4)(b) (4) (b) (4)(b) (4) (b) (4)(b) (4) (b) (4)(b) (4)(b) (4) (b) (4)(b) (4) (b) (4)(b) (4) (b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4)(b) (4) (b) (4)(b) (4) (b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4)	(b) (4)

Attachment 2 – Deliverables Table

Contract Period	WBS Element	Milestone	Deliverable	Success Criteria	Estimated Completion Date
CLIN0001	(b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4) (b) (4)	(b) (4)(b) (4) (b) (4) (b) (4)	(b) (4)(b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4)(b) (4) (b) (4)	(b) (4)(b) (4)(b) (4) (b) (4)(b) (4) (b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4) (b) (4)(b) (4) (b) (4)(b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4)(b) (4) (b) (4)(b) (4) (b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4)(b) (4) (b) (4)(b) (4) (b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4)(b) (4)	(b) (4)
CLIN0001	(b) (4)(b) (4)(b) (4) (b) (4)(b) (4) (b) (4)(b) (4) (b) (4)(b) (4) (b) (4)	(b) (4)(b) (4) (b) (4) (b) (4)	(b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4)(b) (4) (b) (4) (b) (4)(b) (4)(b) (4) (b) (4)	(b) (4)(b) (4)(b) (4) (b) (4)	(b) (4)(b) (4) (b) (4)

Attachment 2 – Deliverables Table

Contract Period	WBS Element	Milestone	Deliverable	Success Criteria	Estimated Completion Date
CLIN0002	Identification(b) (4) (b) (4)(b) (4)(b) (4) (b) (4)(b) (4) (b) (4)	(b) (4)(b) (4) (b) (4)(b) (4) (b) (4)(b) (4) (b) (4)(b) (4)	(b) (4)(b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4)(b) (4) (b) (4)	(b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4)	(b) (4)
CLIN0003	(b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4) (b) (4) (b) (4)	(b) (4)(b) (4) (b) (4) (b) (4)(b) (4) (b) (4) (b) (4)(b) (4) (b) (4)(b) (4) (b) (4)	(b) (4)(b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4)(b) (4) (b) (4)	(b) (4)(b) (4)(b) (4) (b) (4) (b) (4)(b) (4) (b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4) (b) (4)(b) (4) (b) (4)	(b) (4)

Beckman062

Attachment 2 – Deliverables Table

Contract Period	WBS Element	Milestone	Deliverable	Success Criteria	Estimated Completion Date
CLIN0004	(b) (4)(b) (4)(b) (4) (b) (4)(b) (4) (b) (4) (b) (4)	(b) (4) (b) (4)(b) (4) (b) (4) (b) (4) (b) (4) (b) (4)	(b) (4)(b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4)(b) (4)	(b) (4)(b) (4) (b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4)(b) (4) (b) (4)(b) (4) (b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4)	(b) (4)
CLIN0004	(b) (4)(b) (4)(b) (4) (b) (4) (b) (4)	(b) (4) (b) (4) (b) (4)	(b) (4)(b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4)(b) (4) (b) (4)(b) (4) (b) (4)(b) (4)(b) (4)(b) (4) (b) (4)	(b) (4)(b) (4) (b) (4)(b) (4) (b) (4)(b) (4)(b) (4) (b) (4)	(b) (4)
CLIN0005	(b) (4)(b) (4)(b) (4) (b) (4)(b) (4) (b) (4)(b) (4)(b) (4) (b) (4)	(b) (4) (b) (4) (b) (4)(b) (4) (b) (4)(b) (4)	(b) (4)(b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4) (b) (4)	(b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4) (b) (4)(b) (4) (b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4) (b) (4)(b) (4)	(b) (4)

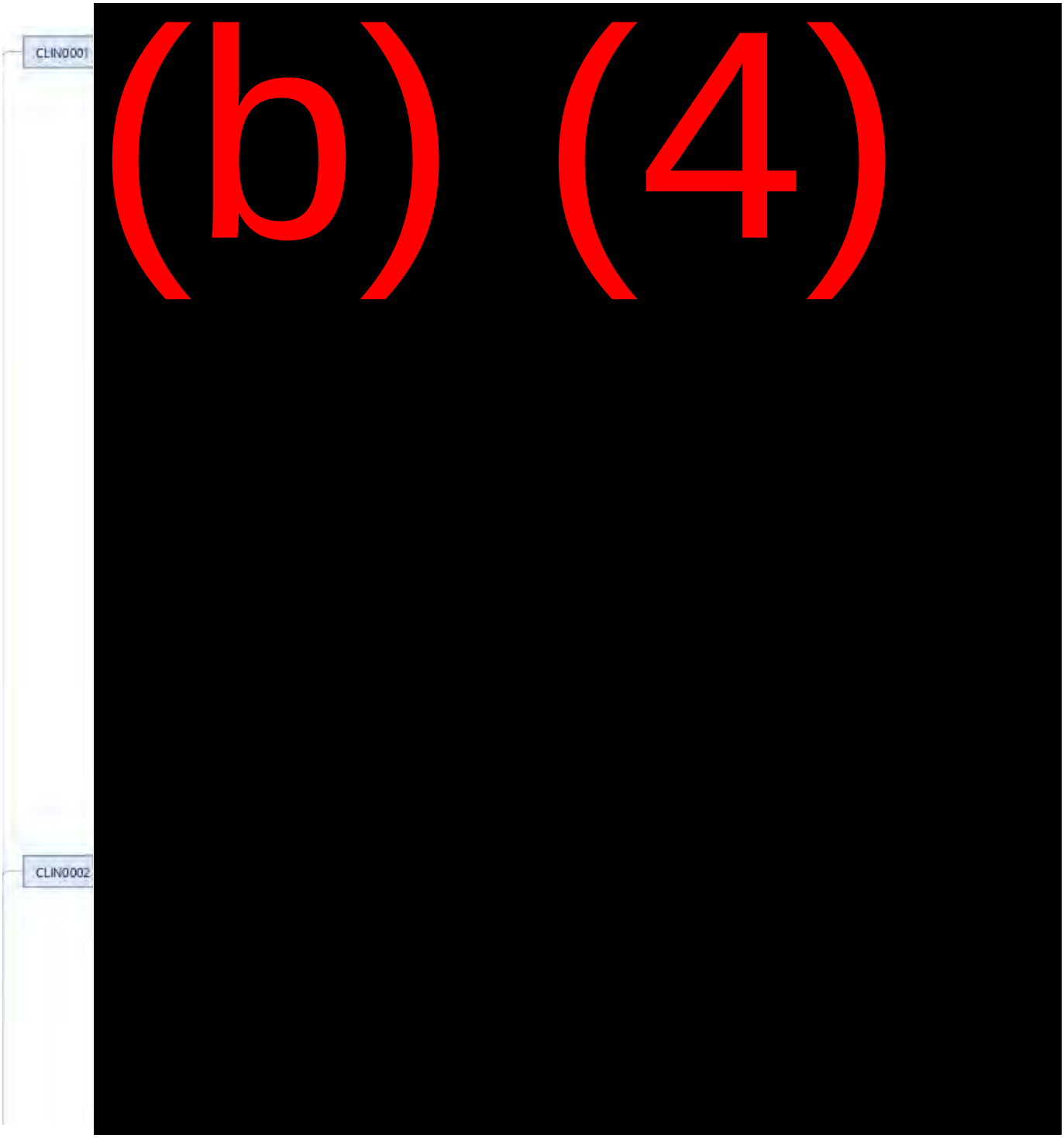
Beckman063

Attachment 2 – Deliverables Table

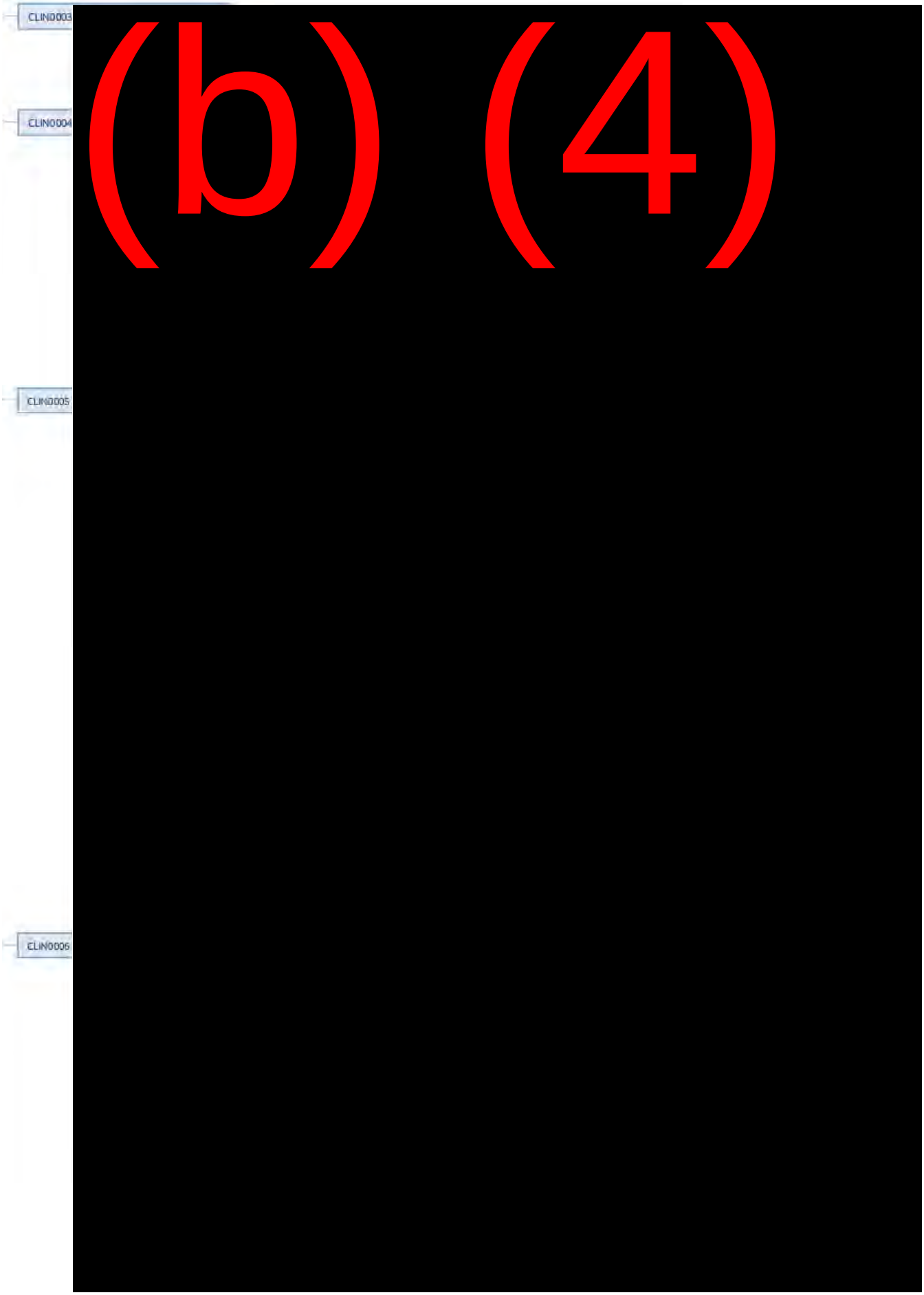
Contract Period	WBS Element	Milestone	Deliverable	Success Criteria	Estimated Completion Date
CLIN0005	(b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4) (b) (4) (b) (4)	(b) (4) (b) (4) (b) (4)(b) (4) (b) (4)(b) (4)	(b) (4)(b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4)(b) (4) (b) (4)	(b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4) (b) (4)(b) (4) (b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4) (b) (4)	(b) (4)
CLIN0005	(b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4) (b) (4) (b) (4)	(b) (4) (b) (4) (b) (4)(b) (4) (b) (4)(b) (4)	(b) (4)(b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4)(b) (4) (b) (4)	(b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4) (b) (4)(b) (4) (b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4) (b) (4)	(b) (4)
CLIN0005	(b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4) (b) (4)(b) (4) (b) (4)	(b) (4)(b) (4) (b) (4)(b) (4)	(b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4)(b) (4) (b) (4)(b) (4)	(b) (4)(b) (4)(b) (4) (b) (4)(b) (4) (b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4) (b) (4)	(b) (4)
CLIN0006	(b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4) (b) (4) (b) (4)	(b) (4)(b) (4) (b) (4)(b) (4)	(b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4)(b) (4) (b) (4) (b) (4)	(b) (4)(b) (4)(b) (4) (b) (4)(b) (4)(b) (4)	(b) (4)

Attachment 2 – Deliverables Table

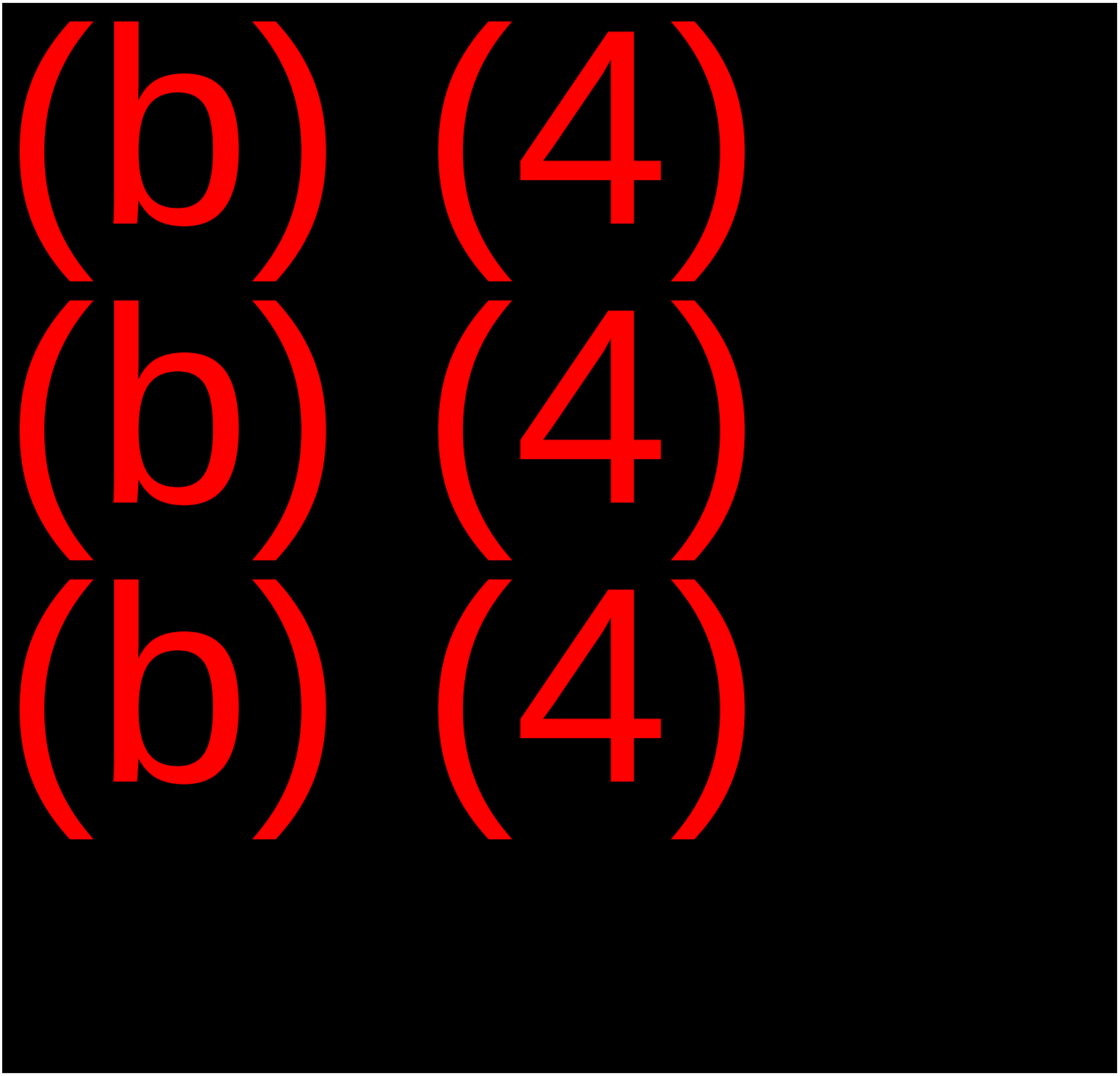
Appendix 1: Work Breakdown Structure (WBS)



Attachment 2 – Deliverables Table

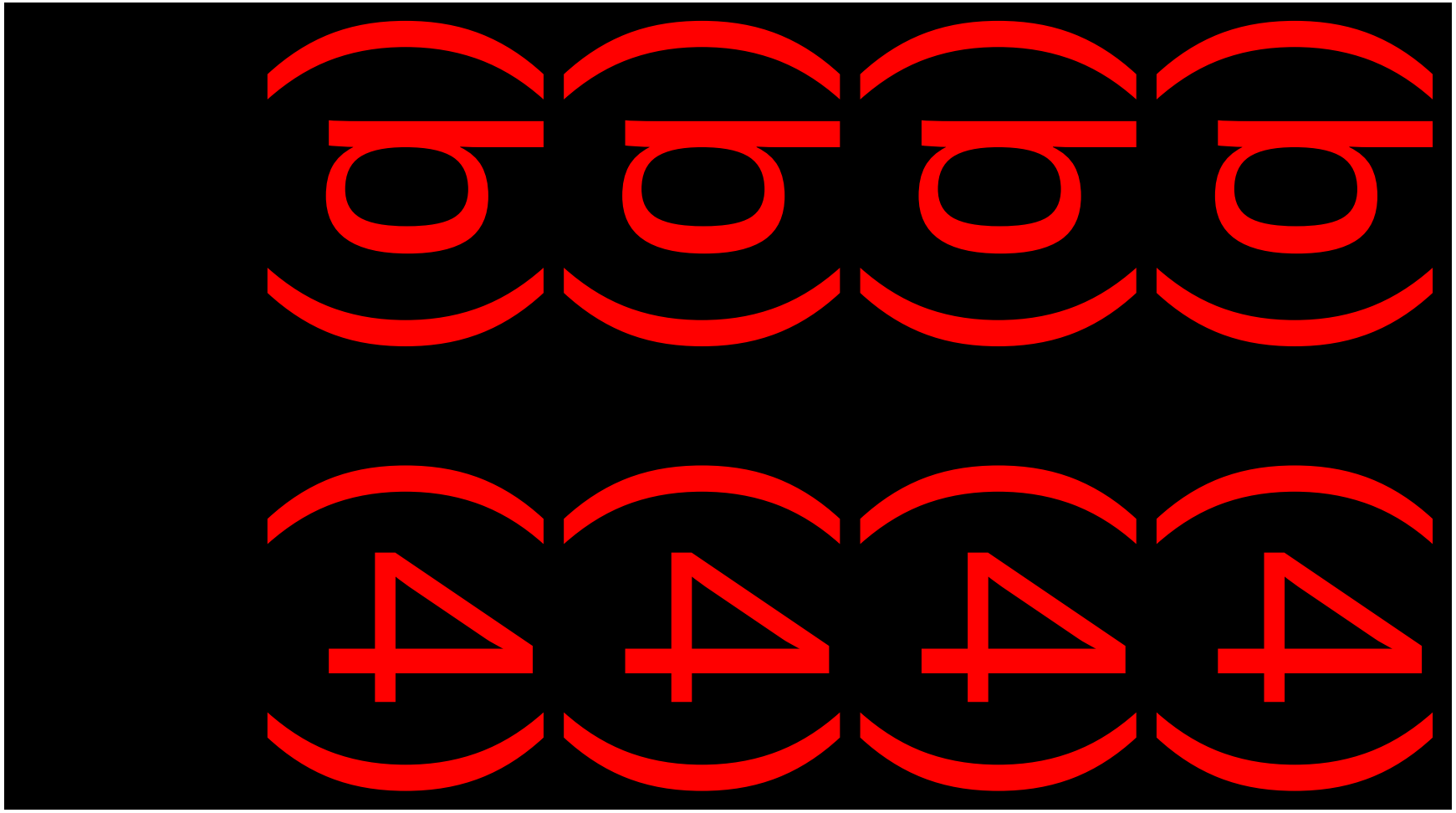


Attachment 2 – Deliverables Table



Attachment 2 – Deliverables Table

Attachment 3 – Go/No Go Milestones & Decision Gating



Timeline Detail:

Base Period	Option Period				
CLIN 0001	CLIN 0002	CLIN 0003	CLIN 0004	CLIN 0005	CLIN 0006
10/1/2019	1/1/2020	1/1/2020	6/1/2020	3/1/2021	1/1/2022
Through	Through	Through	Through	Through	Through
12/31/2021	5/30/2020	9/30/2020	3/1/2021	9/30/2023	9/30/2023

Attachment 3 – Go/No Go Milestones & Decision Gating

Go/No-Go # (per Figure 1 above)	CLIN	Go/No-Go Milestone	Success Criteria	Failure Criteria	Go/No-Go Decision Gate	Trigger for CLIN/ Option
#1	CLIN0001	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

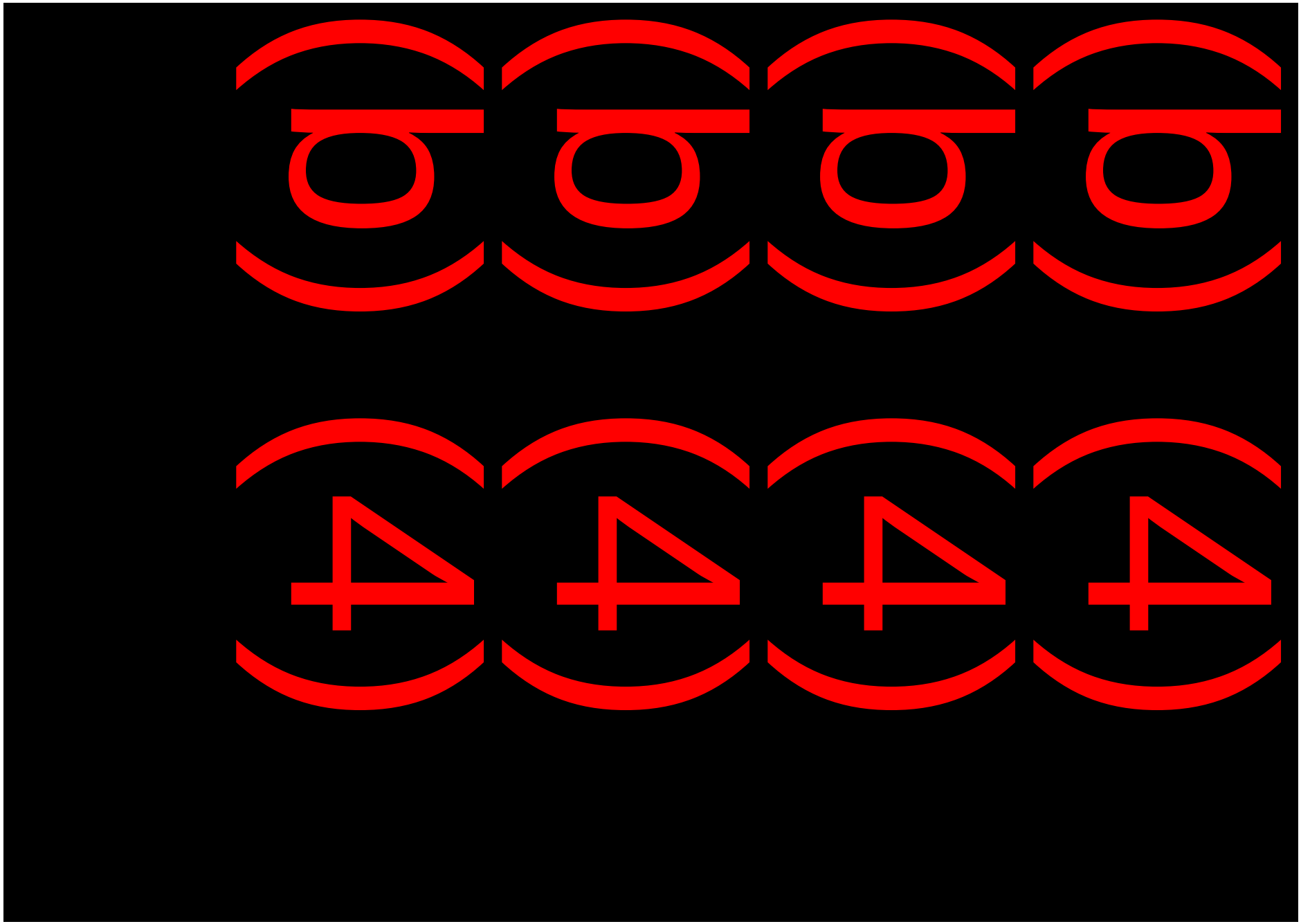
Attachment 3 – Go/No Go Milestones & Decision Gating

Go/No-Go # (per Figure 1 above)	CLIN	Go/No-Go Milestone	Success Criteria	Failure Criteria	Go/No-Go Decision Gate	Trigger for CLIN/ Option
#2	CLIN0001	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
#3	CLIN0002	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Attachment 3 – Go/No Go Milestones & Decision Gating

Go/No-Go # (per Figure 1 above)	CLIN	Go/No-Go Milestone	Success Criteria	Failure Criteria	Go/No-Go Decision Gate	Trigger for CLIN/ Option
#4	CLIN0004	(b) (4)	(b) (4)			

Attachment 3 – Go/No Go Milestones & Decision Gating



Attachment 3 – Go/No Go Milestones & Decision Gating

Go/No-Go # (per Figure 1 above)	CLIN	Go/No-Go Milestone	Success Criteria	Failure Criteria	Go/No-Go Decision Gate	Trigger for CLIN/ Option
			[redacted]			

***Relevant to all Milestones:** Per Beckman Coulter new product development standard work, all success criteria will have quantitative design requirements associated with them which will be shared with BARDA for review

Attachment 4 – Data Assertion Table

Description of Technical Data or Computer Software	Deliverable?	Government License Rights	Basis for Assertion
1. Teleconference kickoff meeting focused on the contract and a face to face kick-off meeting that will be focused on the technical components of this contract	Yes	Unlimited	FAR 52.227-14 Rights in Data – General
2. Monthly teleconferences with BARDA to discuss the performance of the contract	Yes	Unlimited	FAR 52.227-14 Rights in Data – General
3. Face to Face meetings for program review as designated by the COR. These meetings will be used to discuss contract progress in relation to the program management deliverables described in this Contract and SOW as well as study designs, regulatory and manufacturing updates	Yes	Unlimited	FAR 52.227-14 Rights in Data – General
4. Monthly technical progress reports describing project progress over the previous month	Yes	Limited with respect to algorithm-related data Unlimited with respect to other data	Developed at private expense/cost-sharing contract FAR 52.227-14 Rights in Data – General
5. Any manuscript, scientific meeting abstract, scientific presentation or press release containing data generated under this Contract or referencing the technical work performed under this contract must be submitted to BARDA for review prior to submission	Yes	Limited with respect to algorithm-related data Unlimited with respect to other data	Developed at private expense/cost-sharing contract FAR 52.227-14 Rights in Data – General
6. Final data package consisting of all raw data produced under this Contract. This submission package must be delivered in a non-proprietary format. If clinical trial data is included, that data must be provided consistent with applicable	Yes	Limited with respect to algorithm-related data Unlimited with respect to other data	Developed at private expense/cost-sharing contract FAR 52.227-14 Rights in Data – General

	privacy laws to protect personally identifiable information (PII)			
7.	Draft final report and final report are to include a summation of the work performed and results obtained for the entire Contract period of performance and shall be in sufficient detail to describe comprehensively the results achieved. The reports shall include the following sections: Cover Page, Executive Summary and Results. The Draft Final Report will be submitted to the COR and CO who will review the Draft Final Report and provide the Contractor with comments. The Final Report shall include or address the COR's and CO's written comments on the draft report. Note: There will be one Final Report due at the end of the Base Period and one Final Report encompassing the entire contract due upon completion of the Option Period, if exercised	Yes	Limited with respect to algorithm-related data Unlimited with respect to other data	Developed at private expense/cost-sharing contract FAR 52.227-14 Rights in Data – General
8.	[redacted] (b) (4)	Yes	Limited	Developed at private expense/cost-sharing contract
9.	[redacted] (b) (4)	Yes	Unlimited	FAR 52.227-14 Rights in Data – General

Attachment 4 – Data Assertion Table

10. Meeting minutes from pre-sub meeting with the FDA and detailed plan for FDA submission (Task 1.2)	Yes	Unlimited	FAR 52.227-14 Rights in Data – General
11. Meeting minutes from pre-sub meeting with the FDA (Task 1.3)	Yes	Unlimited	FAR 52.227-14 Rights in Data – General
12. A [redacted]	Yes	Limited	Developed at private expense/cost-sharing contract
13. [redacted]	Yes	Limited	Developed at private expense/cost-sharing contract
14. FDA 510(k) or de novo submission package [redacted]	Yes	Unlimited	FAR 52.227-14 Rights in Data – General
15. FDA clearance of [redacted]	Yes	Unlimited	FAR 52.227-14 Rights in Data – General
16. [redacted]	Yes	Limited	Developed at private expense/cost-sharing contract
17. Report on the calibrator and controls R&D reproducibility experiments	Yes	Unlimited	FAR 52.227-14 Rights in Data – General
18. [redacted]	Yes	Limited	Developed at private expense/cost-sharing contract
19. [redacted]	Yes	Unlimited	FAR 52.227-14 Rights in Data – General

Attachment 4 – Data Assertion Table

20. A clinical study and analytical report of the analysis of the hematology parameters' performance for sepsis detection	Yes	Unlimited	FAR 52.227-14 Rights in Data – General
21. A clinical study and analytical report of the analysis of the machine learning algorithm performance for sepsis detection [redacted]	Yes	Limited	Developed at private expense/cost-sharing contract
22. A clinical study and analytical report of the analysis of the machine learning algorithm performance for sepsis prediction in [redacted]	Yes	Limited	Developed at private expense/cost-sharing contract
23. A report of the usage of the production and research platforms for the duration of the contract period	Yes	Unlimited	FAR 52.227-14 Rights in Data – General
24. [redacted]	Yes	Unlimited	FAR 52.227-14 Rights in Data – General
25. Preexisting technology/non-deliverables/non-deliverable improvements, including but not limited to, improvements to algorithms	No	None	Developed at private expense/cost-sharing contract/minor modifications/non-deliverable

Attachment 5

SAMPLE INVOICE/PAYMENT REQUEST AND CONTRACT FINANCIAL REPORT

(a) Designated Billing Office Name and Address: DHHS/OS/ASPR/BARDA Attn: Contracting Officer 330 Independence Ave., S.W. Room G644 Washington, D.C. 20201 (b) Contractor's Name, Address, Point of Contact, VIN, and DUNS or DUNS+4 Number: ABC CORPORATION 100 Main Street Anywhere, USA Zip Code Name, Title, Phone Number, and E-mail Address of person to notify in the event of an improper invoice or, in the case of payment by method other than Electronic Funds Transfer, to whom payment is to be sent. **VIN:** **DUNS or DUNS+4:**	(c) Invoice/Financing Request No.: (d) Date Invoice Prepared: (e) Contract No. and Order No. (if applicable): _____ (f) Effective Date: (g) Total Estimated Cost of Contract/Order: (h) Total Fixed-Fee (if applicable): (i) ☐Two-Way Match: ☐Three-Way Match: (j) Office of Acquisitions: (k) Central Point of Distribution:

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

Expenditure Category* A	Cumulative Percentage of Effort/Hrs. Negotiated B	Actual C	Amount Billed (m) Current D	(n) Cumulative E	Cost at Completion F	Contract Amount G	Variance H
(o) Direct Costs:							
(1)Direct Labor							
(2)Fringe Benefits							
(3)Accountable Property							
(4)Materials & Supplies							
(5)Premium Pay							
(6)Consultant Fees							
(7) Travel							
(8)Subcontracts							
(9)Other							
Total Direct Costs							
(q) Indirect Costs							
(r) Subtotal							
(s) Adjustments							
(t) Total Allowable Costs							
(u) Less Contractor Cost-Share							
(v) Total Amount							

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

_____ _____

(Name of Official) (Title)

* Attach details as specified in the contract

Format: Payment requests shall be submitted on the Contractor's self-generated form in the manner and format prescribed herein and as illustrated in the Sample Invoice/Financing Request. Standard Form 1034, Public Voucher for Purchases and Services Other Than Personal, may be used in lieu of the Contractor's self-generated form provided it contains all of the information shown on the Sample Invoice/Financing Request. DO NOT include a cover letter with the payment request.

Number of Copies: Payment requests shall be submitted in the quantity specified in the Invoice Submission Instructions in Section G of the Contract Schedule.

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

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

Billing of Costs Incurred: If billed costs include (1) costs of a prior billing period, but not previously billed, or (2) costs incurred during the contract period and claimed after the contract period has expired, the Contractor shall site the amount(s) and month(s) in which it incurred such costs.

Contractor's Fiscal Year: Payment requests shall be prepared in such a manner that the Government can identify costs claimed with the Contractor's fiscal year.

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

Costs Requiring Prior Approval: Costs requiring the Contracting Officer's approval, including those set forth in an Advance Understanding in the contract, shall be identified and reference the Contracting Officer's Authorization (COA) Number. In addition, the Contractor shall show any cost set forth in an Advance Understanding as a separate line item on the payment request.

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

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

(b) **Completion Invoice:** The completion invoice shall be submitted promptly upon completion of the work, but no later than one year from the contract completion date, or within 120 days after settlement of the final indirect cost rates covering the year in which the contract is physically complete (whichever date is later). The Contractor shall submit the completion invoice when all costs have been assigned to the contract and it completes all performance provisions.

(c) **Final Invoice:** A final invoice may be required after the amounts owed have been settled between the Government and the Contractor (e.g., resolution of all suspensions and audit exceptions).

Preparation and Itemization of the Invoice/Financing Request: The Contractor shall furnish the information set forth in the instructions below. The instructions are keyed to the entries on the Sample Invoice/Financing Request.

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

(b) **Contractor's Name, Address, Point of Contact, VIN, and DUNS or DUNS+4 Number:** Show the

Contractor's name and address exactly as they appear in the contract, along with the name, title, phone number, and e-mail address of the person to notify in the event of an improper invoice or, in the case of payment by method other than Electronic Funds Transfer, to whom payment is to be sent. Provide the Contractor's Vendor Identification Number (VIN), and Data Universal Numbering System (DUNS) number or DUNS+4. The DUNS number must identify the Contractor's name and address exactly as stated on the face page of the contract. When an approved assignment has been made by the Contractor, or a different payee has been designated, provide the same information for the payee as is required for the Contractor (i.e., name, address, point of contact, VIN, and DUNS).

(c) **Invoice/Financing Request Number:** Insert the appropriate serial number of the payment request.

(d) **Date Invoice/Financing Request Prepared:** Insert the date the payment request is prepared.

(e) **Contract Number and Order Number (if applicable):** Insert the contract number and order number (if applicable).

(f) **Effective Date:** Insert the effective date of the contract or if billing under an order, the effective date of the order.

(g) **Total Estimated Cost of Contract/Order:** Insert the total estimated cost of the contract, exclusive of fixed-fee. If billing under an order, insert the total estimated cost of the order, exclusive of fixed-fee. For incrementally funded contracts/orders, enter the amount currently obligated and available for payment.

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

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

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

(k) **Billing Period:** Insert the beginning and ending dates (month, day, and year) of the period in which costs were incurred and for which reimbursement is claimed.

(l) **Amount Billed - Current Period:** Insert the amount claimed for the current billing period by major cost element, including any adjustments and fixed-fee. If the Contract Schedule contains separately priced line items, identify the contract line item(s) on the payment request and include a separate breakdown (by major cost element) for each line item.

(m) **Amount Billed - Cumulative:** Insert the cumulative amounts claimed by major cost element, including any adjustments and fixed-fee. If the Contract Schedule contains separately priced line items, identify the contract line item(s) on the payment request and include a separate breakdown (by major cost element) for each line item.

(n) **Direct Costs:** Insert the major cost elements. For each element, consider the application of the paragraph entitled "Costs Requiring Prior Approval" on page 1 of these instructions.

(1) **Direct Labor:** Include salaries and wages paid (or accrued) for direct performance of the contract. List individuals by name, title/position, hourly/annual rate, level of effort (actual hours or % of effort), breakdown by task performed by personnel, and amount claimed.

(2) **Fringe Benefits:** List any fringe benefits applicable to direct labor and billed as a direct cost. Do not include in this category fringe benefits that are included in indirect costs.

(3) **Accountable Personal Property:** Include any property having a unit acquisition cost of $5,000 or more, with a life expectancy of more than two years, and sensitive property regardless of cost (see the HHS *Contractor's Guide for Control of Government Property*)(e.g. personal computers). Note this is not permitted for reimbursement without pre-authorization from the CO.

On a separate sheet of paper attached to the payment request, list each item for which reimbursement is requested. Include reference to the following (as applicable):

- item number for the specific piece of equipment listed in the Property Schedule, and
- COA number, if the equipment is not covered by the Property Schedule.

The CO may require the Contractor to provide further itemization of property having specific limitations set forth in the contract.

(4) **Materials and Supplies:** Include all consumable material and supplies regardless of amount. Detailed line-item breakdown (e.g. receipts, quotes, etc.) is required.

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

(6) **Consultant Fee:** List fees paid to consultants. Identify consultant by name or category as set forth in the contract or COA, as well as the effort (i.e., number of hours, days, etc.) and rate billed.

(7) **Travel:** N/A under this award.

(8) **Subcontract Costs:** List subcontractor(s) by name and amount billed. Provide subcontract invoices/receipts as backup documentation. If subcontract is of the cost-reimbursement variety, detailed breakdown will be required. Regardless, include backup documentation (e.g. subcontractor invoices, quotes, etc.).

(9) **Other:** Include all other direct costs not fitting into an aforementioned category. If over $1,000, list cost elements and dollar amounts separately. If the contract contains restrictions on any cost element, that cost element must be listed separately.

(o) **Cost of Money (COM):** Cite the COM factor and base in effect during the time the cost was incurred and for which reimbursement is claimed, if applicable.

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

(q) **Subtotals:** Insert the total amounts claimed for the current and cumulative periods.

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

(s) **Total Allowable Costs**

(t) **Contractor Cost-Share:** Include the contractor cost-shares.

(u) **Certification of Salary Rate Limitation:** If required by the contract (see Invoice Submission Instructions in Section G of the Contract Schedule), the Contractor shall include the following certification at the bottom of the payment request:

"I hereby certify that the salaries billed in this payment request are in compliance with the Salary Rate Limitation Provisions in Section H of the contract."

**Note the CO may require the Contractor to submit detailed support for costs claimed on payment requests. Every

cost must be determined to be allocable, reasonable, and allowable per FAR Part 31.