

AWARD/CONTRACT	1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)	RATING	PAGE OF PAGES 1 4
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2. CONTRACT (Proc. Inst. Ident.) NO. 75A50120C00094	3. EFFECTIVE DATE See Block 20C	4. REQUISITION/PURCHASE REQUEST/PROJECT NO. OS257766
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5. ISSUED BY CODE ASPR-BARDA ASPR-BARDA 200 Independence Ave., S.W. Room 640-G Washington DC 20201	6. ADMINISTERED BY (If other than Item 5) CODE ASPR-BARDA ASPR-BARDA US DEPT OF HEALTH & HUMAN SERVICES BIOMEDICAL ADVANCED RESEACH & DEVELOPMENT AUT 200 INDEPENDENCE AVE, S.W. Washington DC 20201 SCD-C
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7. NAME AND ADDRESS OF CONTRACTOR (No., street, country, State and ZIP Code) America's Blood Centers 1717 K Street NW Suite 900 Washington, DC 20006	8. DELIVERY <input type="checkbox"/> FOB ORIGIN <input checked="" type="checkbox"/> OTHER (See below)
	9. DISCOUNT FOR PROMPT PAYMENT
	10. SUBMIT INVOICES (4 copies unless otherwise specified) TO THE ADDRESS SHOWN IN ITEM

11. SHIP TO/MARK FOR CODE HHS/OS/ASPR HHS/OS/ASPR 200 C St SW WASHINGTON DC 20201	12. PAYMENT WILL BE MADE BY CODE PSC PSC Program Support Center 7700 Wisconsin Ave Bethesda MD 20814
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13. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION: <input type="checkbox"/> 10 U.S.C. 2304 (c) () <input checked="" type="checkbox"/> 41 U.S.C. 3304 (a) ()	14. ACCOUNTING AND APPROPRIATION DATA 2020.199C002.25106
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15A. ITEM NO	15B. SUPPLIES/SERVICES	15C. QUANTITY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT
Continued					

15G. TOTAL AMOUNT OF CONTRACT \$750,000.00

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

17. <input checked="" type="checkbox"/> CONTRACTOR'S NEGOTIATED AGREEMENT (Contractor is required to sign this document and return <u>1</u> 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. <input type="checkbox"/> 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.)
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19A. NAME AND TITLE OF SIGNER (Type or print)	19B. NAME OF CONTRACTOR BY Katherine Fry (Signature of person authorized)	19C. DATE SIGNED	20B. UNITED STATES OF AMERICA BY Jeffrey R. Schmidt -S (Signature of the Contracting Officer)	20C. DATE SIGNED Digitally signed by Jeffrey R. Schmidt -S Date: 2020.04.17 18:34:05 -04'00'
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NAME OF OFFEROR OR CONTRACTOR

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	<p>Tax ID Number: 86-6052376 DUNS Number: Not Available This is a Letter Contract issued in accordance with FAR 16.603 and HHSAR 316.603.</p> <p>The purpose of this Letter Contract and eventual definitive contract is to acquire convalescent plasma units and the support and coordination services required to deliver those units. America's Blood Centers (the Contractor) and the Government will enter into a definitive contract for the services using the commercial procedures describe in FAR Part 12.</p> <p>The relevant activities of this letter contract and eventual definitive contract include (but are not limited to):</p> <p>(a) Support and coordination services among blood centers to include:</p> <p>(1) Donor files with all documentation supporting eligibility. (2) Qualification of donors for collection. (3) Connection of donors to nearest collection site(s) to collect unit. (4) Coordination of samples or segments from donors. (5) Recruitment of donors. (6) Maintaining information regarding units collected and instruct blood centers regarding release of product based on Government-provided protocol. (7) Facilitate reimbursement of collecting sites. (8) Refer investigators to the Expanded Access Protocol as appropriate. (9) Maintain system to facilitate the link between the donated unit and the facility receiving the investigational unit.</p> <p>(b) Support and coordination of delivery of convalescent plasma units (i.e., verification, collection processing, storage, and distribution) for use in the Expanded Access Protocol and other federally funded COVID19 efforts as directed by BARDA.</p> <p>The period of performance of the definitive contract must not exceed one-year.</p> <p>The ceiling for this Letter Contract is \$750,000; the Contractor exceeds this ceiling at its own Continued ...</p>				

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NAME OF OFFEROR OR CONTRACTOR

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	<p>risk.</p> <p>The following clauses are incorporated by full text:</p> <p>FAR 52.216-24 Limitation of Government Liability. (a) In performing this contract, the Contractor is not authorized to make expenditures or incur obligations exceeding \$750,000 dollars. (b) The maximum amount for which the Government shall be liable if this contract is terminated is \$375,000 dollars. (End of clause)</p> <p>FAR 52.216-25, Contract Definitization. (a) A time-and-materials and/or fixed-price definitive contract is contemplated. The Contractor agrees to begin promptly negotiating with the Contracting Officer the terms of a definitive contract that will include (1) all clauses required by the Federal Acquisition Regulation (FAR) on the date of execution of the contract, (2) all clauses required by law on the date of execution of the definitive contract, and (3) any other mutually agreeable clauses, terms, and conditions. The Contractor agrees to submit a time-and-materials and/or fixed-price proposal, including data other than certified cost or pricing data, and certified cost or pricing data, in accordance with FAR 15.408, Table 15-2, supporting its proposal. (b) The schedule for definitizing this contract is: Proposal submission: NLT May 1, 2020 Negotiations: NLT May 8, 2020 Award: NLT May 15, 2020 (c) If agreement on a definitive contract to supersede this letter contract is not reached by the target date in paragraph (b) of this section, or within any extension of it granted by the Contracting Officer, the Contracting Officer may, with the approval of the head of the contracting activity, determine a reasonable price or fee in accordance with subpart 15.4 and part 31 of the FAR, subject to Contractor appeal as provided in the Disputes clause. In any event, the Contractor shall proceed with completion of the contract, subject only to the Limitation of Government Liability clause. (1) After the Contracting Officer's determination Continued ...</p>				

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NAME OF OFFEROR OR CONTRACTOR

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
1	<p>of price or fee, the contract shall be governed by-</p> <p>i. All clauses required by the FAR on the date of execution of this letter contract for either fixed-price or cost-reimbursement contracts, as determined by the Contracting Officer under this paragraph (c);</p> <p>ii. All clauses required by law as of the date of the Contracting Officer's determination; and</p> <p>iii. Any other clauses, terms, and conditions mutually agreed upon.</p> <p>(2) To the extent consistent with paragraph (c) (1) of this section, all clauses, terms, and conditions included in this letter contract shall continue in effect, except those that by their nature apply only to a letter contract. (End of clause)</p> <p>Delivery: 04/19/2020 Appr. Yr.: 2020 CAN: 199C002 Object Class: 25106 Period of Performance: 04/17/2020 to 04/16/2021</p> <p>ASPR-20-02015 -- COVID 19 - Convalescent plasma units and the support and coordination services required to deliver those units. Obligated Amount: \$750,000.00</p>				750,000.00

2. AMENDMENT/MODIFICATION NO. P00001	3. EFFECTIVE DATE See Block 16C	4. REQUISITION/PURCHASE REQ. NO. OS258518	5. PROJECT NO. (If applicable)
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6. ISSUED BY ASPR-BARDA 200 Independence Ave., S.W. Room 640-G Washington DC 20201	7. ADMINISTERED BY (If other than Item 6) ASPR-BARDA US DEPT OF HEALTH & HUMAN SERVICES BIOMEDICAL ADVANCED RESEACH & DEVELOPMENT AUT 200 INDEPENDENCE AVE, S.W. Washington DC 20201
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8. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and ZIP Code) AMERICA'S BLOOD CENTERS 1559070 725 15TH ST NW STE 700 WASHINGTON DC 200052109	9A. AMENDMENT OF SOLICITATION NO. 9B. DATED (SEE ITEM 11) 10A. MODIFICATION OF CONTRACT/ORDER NO. 75A50120C00094 10B. DATED (SEE ITEM 13) 04/17/2020
CODE 1559070 FACILITY CODE	

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers is extended. is not extended. Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or electronic communication which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by letter or electronic communication, provided each letter or electronic communication makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required) Net Increase: \$15,039,606.00
See Schedule

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

CHECK ONE	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation data, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
X	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: FAR 52.216-25, CONTRACT DEFINITIZATION.
	D. OTHER (Specify type of modification and authority)

E. IMPORTANT: Contractor is not is required to sign this document and return 1 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)
Tax ID Number: 86-6052376
DUNS Number: 194910121
The purpose of this modification is to definitize Letter Contract No. 75A50120C00094 entered into with the America's Blood Centers on April 17, 2020.
This modification fully funds the base performance of the contract.

The following attachments are applicable to this order and incorporated by appendix:
1. Statement of Work.
2. Contract Administration.
3. Reporting and Meeting Requirements.
Continued ...

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

15A. NAME AND TITLE OF SIGNER (Type or print) Katherine Fry	16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) JEFFREY R. SCHMIDT
15B. CONTRACTOR/OFFEROR Katherine Fry (b)(6)	16B. UNITED STATES OF AMERICA Jeffrey R. Schmidt -S
15C. DATE SIGNED 5/20/2020	16C. DATE SIGNED Digitally signed by Jeffrey R. Schmidt -S Date: 2020.05.20 19:32:34 -04'00'

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NAME OF OFFEROR OR CONTRACTOR
AMERICA'S BLOOD CENTERS 1559070

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
1	<p>4. Special Contract Requirements. 5. Addendum to FAR 52.212-4, Terms and Conditions--Commercial Items. 6. FAR 52.212-5, Contract Terms and Conditions Required to Implement Statutes or Executive Orders--Commercial Items. 7. BARDA Firm Fixed Price Invoice Instructions.</p> <p>Delivery Location Code: HHS/OS/ASPR HHS/OS/ASPR 200 C St SW WASHINGTON DC 20201 US</p> <p>Period of Performance: 04/17/2020 to 04/16/2021</p> <p>Change Item 1 to read as follows(amount shown is the obligated amount):</p> <p>Startup costs for blood collection sites</p> <p>This is a firm-fixed-price contract line. The contractor can invoice upon execution of this modification in accordance with the INVOICING paragraph in Attachment 2 - Contract Administration. Obligated Amount: \$0.00</p> <p>Accounting Info: 2020.199C002.25106 Appr. Yr.: 2020 CAN: 199C002 Object Class: 25106 Funded: \$0.00</p> <p>Add Item 2 as follows:</p>				0.00
2	<p>Startup costs for blood collection sites</p> <p>This is a firm-fixed-price contract line. The contractor can invoice upon execution of this modification and in accordance with the INVOICING paragraph in Attachment 2 - Contract Administration. Obligated Amount: \$3,452,323.00</p> <p>Accounting Info: 2020.199C002.25103 Appr. Yr.: 2020 CAN: 199C002 Object Class: 25103 Funded: \$3,452,323.00 Continued ...</p>				3,452,323.00

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NAME OF OFFEROR OR CONTRACTOR
AMERICA'S BLOOD CENTERS 1559070

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
3	<p>Add Item 3 as follows:</p> <p>ABC & BCA startup costs.</p> <p>This is a firm-fixed-price contract line. The contractor can invoice upon execution of this modification and in accordance with the INVOICING paragraph in Attachment 2 - Contract Administration.</p> <p>Obligated Amount: \$112,283.00</p> <p>Accounting Info: 2020.199C002.25103 Appr. Yr.: 2020 CAN: 199C002 Object Class: 25103 Funded: \$112,283.00</p> <p>Add Item 4 as follows:</p>				112,283.00
4	<p>Units of convalescent plasma (b)(4)</p> <p>This is a firm-fixed-price contract line. The contractor can invoice on a per unit basis following shipment of that unit and in accordance with the INVOICING paragraph in Attachment 2 - Contract Administration.</p> <p>Obligated Amount: \$7,650,000.00</p> <p>Accounting Info: 2020.199C002.25103 Appr. Yr.: 2020 CAN: 199C002 Object Class: 25103 Funded: \$7,650,000.00</p> <p>Add Item 5 as follows:</p>				7,650,000.00
5	<p>Units of convalescent plasma for HiG use (b)(4)</p> <p>(b)(4)</p> <p>This is a firm-fixed-price contract line. The contractor can invoice on a per unit basis following shipment of that unit and in accordance with the INVOICING paragraph in Attachment 2 - Continued ...</p>				3,825,000.00

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NAME OF OFFEROR OR CONTRACTOR
AMERICA'S BLOOD CENTERS 1559070

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	Contract Administration. Obligated Amount: \$3,825,000.00 Accounting Info: 2020.199C002.25103 Appr. Yr.: 2020 CAN: 199C002 Object Class: 25103 Funded: \$3,825,000.00 Add Item 6 as follows:				
6	Option 1: Collect and deliver (b)(4) of convalescent plasma to hospitals and medical centers participating in the Expanded Access Protocol administered by the Mayo Clinic. Amount: \$8,415,000.00 (Option Line Item) Add Item 7 as follows:	(b)(4)	EA	(b)(4)	0.00
7	Option 2: Collect and deliver (b)(4) of convalescent plasma to hospitals and medical centers participating in the Expanded Access Protocol administered by the Mayo Clinic (repeatable (b)(4)) Amount: \$9,945,000.00 (Option Line Item) Add Item 8 as follows:		EA		0.00
8	Option 3: Collect and deliver (b)(4) of convalescent plasma to hospitals and medical centers participating in the Expanded Access Protocol administered by the Mayo Clinic (repeatable (b)(4)) Amount: \$15,300,000.00 (Option Line Item) Add Item 9 as follows:		EA		0.00
9	Option 4: Collect and deliver (b)(4) of convalescent plasma to hospitals and medical centers participating in the Expanded Access Protocol administered by the Mayo Clinic (repeatable (b)(4)) Amount: \$22,950,000.00 (Option Line Item) Add Item 10 as follows:		EA		0.00
10	Option 5: Collect and deliver (b)(4) convalescent plasma to Grifols for use in manufacturing hyperimmune globulin products (b)(4) over Continued ...		EA		0.00

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NAME OF OFFEROR OR CONTRACTOR
AMERICA'S BLOOD CENTERS 1559070

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	<p>a time frame to be determined and agreed upon by BARDA and ABC. Initiation of activity to be determined (repeatable (b)(4)) Amount: \$5,737,500.00 (Option Line Item)</p> <p>Add Item 11 as follows:</p>				
11	<p>Option 6: Collect and deliver (b)(4) of convalescent plasma to Emergent for use in manufacturing hyperimmune globulin products (b)(4) (b)(4) (b)(4) over a time frame to be determined and agreed upon by BARDA and ABC. Initiation of activity to be determined (repeatable (b)(4)) Amount: \$5,737,500.00 (Option Line Item)</p> <p>Add Item 12 as follows:</p>	(b)(4)	EA	(b)(4)	0.00
12	<p>Option 7: Collect and deliver (b)(4) of pathogen reduced convalescent plasma for use in a randomized clinical trial funded by the National Heart, Lung, and Blood Institute at the National Institutes of Health entitled "Clinical-trial of COVID-19 Convalescent Plasma in Outpatients (C3PO)" and executed by is the "Strategies to Innovate EmergENcy Care Clinical Trials Network (SIREN)". Amount: \$600,000.00 (Option Line Item)</p> <p>Add Item 13 as follows:</p>		EA		0.00
13	<p>Option 8: Shipping for units to testing facility and titer testing using a neutralizing antibody test for up to (b)(4) (repeatable (b)(4)) (b)(4).</p> <p>Amount: \$6,000,000.00 (Option Line Item)</p>		EA		0.00

STATEMENT OF WORK

Support and Coordination Services of COVID-19 Convalescent Plasma

I. BACKGROUND INFORMATION AND OBJECTIVES

A. Background Information.

The COVID-19 pandemic has introduced previously unknown challenges in health care and extensive supply shortages. To date, there are no licensed therapies to help alleviate the burden of critically ill patients. There have been some recent studies, however, that have indicated that convalescent plasma may have a positive therapeutic effect.

The United States Government has a need to support and coordinate the verification, collection, storage, and distribution of convalescent plasma units from patients that have recovered from COVID-19. The requirement is for the support and coordination activities as well as the purchase of convalescent plasma units for distribution. It is anticipated that this need will be sustained for approximately one year.

The Government acknowledges that ABC (b)(4)

(b)(4)

B. Technical Objectives.

Technical objectives include support and coordination services among blood centers and support and coordination of delivery of convalescent plasma units.

II. SERVICES TO BE PERFORMED – BASE PERIOD

Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the Statement of Work below:

A. Donor files with all supporting documentation.

All donor files will be maintained by individual blood collectors per FDA regulations in accordance with a Participation Agreement. ABC (b)(4) will not play a supporting/coordinating role in this area.

B. Qualification of donors for collection.

Qualification of donors for collection is the responsibility of each blood collection facility. All participating blood collectors are registered/licensed with the FDA and compliant with FDA requirements for GMP collection, manufacturing and distribution of blood products, including CCP (<https://www.fda.gov/vaccines-blood-biologics/investigational-new-drug-ind-or-device-exemption-ide-process-cber/recommendations-investigational-covid-19-convalescent-plasma> and <https://www.fda.gov/media/136798/download>). ABC (b)(4) will ensure uniform and

consistent language regarding the blood collectors' agreement to comply with all applicable laws, rules, regulations, and guidelines referenced in Investigational COVID-19 Convalescent

Plasma Guidance for Industry is included in all center submissions for reimbursement.

C. Connection of donors to nearest collection site(s) to collect unit.

Through the ABC zip code locator as well as the zip code locator at www.covidplasma.org, ABC will facilitate the connection of donors to the nearest convenient collection site. Additional connections will occur directly between blood collectors and possible donors in their service areas.

D. Coordination of samples or segments from donors.

ABC will assist in the coordination of plasma retains by blood collectors for CCP units distributed to hospitals participating in the Mayo EAP. Per FDA recommendations, blood collectors are storing a retention sample from the convalescent plasma donation for eventual measurement of neutralizing antibody titers. The blood collectors will either perform neutralizing testing for the units shipped or forward the testing data to Mayo Clinic's EAP study or they will ship retention samples to Mayo Clinic's EAP study. Costs associated with the samples for EAP use are included in the reimbursement section below.

E. Recruitment of donors.

The recruitment of donors is being handled by the individual blood collection facilities in their service areas. ABC is working with national partners on national messaging related to CCP and will assist additional efforts as needed.

F. Maintain information regarding units collected and instruct blood centers regarding release of product based on Government-provided protocol.

Supporting documentation for CCP units submitted to BARDA for reimbursement will be retained by (b)(4). Blood centers will release product based on FDA recommendations; ABC, (b)(4) will not be involved in this activity.

G. Reimbursement of blood centers' start-up costs as appropriate.

ABC will facilitate reimbursement of blood centers' start-up costs through a subcontract with (b)(4). Start-up costs not submitted to (b)(4) prior to May 5 will not be reimbursed.

H. Refer investigators to the Expanded Access Protocol as appropriate.

ABC will refer investigators as needed to the appropriate staff at Mayo administering the Expanded Access Protocol.

I. Maintain system to facilitate the link between the donated unit and the facility receiving the investigational unit.

ABC/BCA will maintain documentation supporting the collection and distribution of CCP units by blood collection facilities to hospitals participating in the Mayo EAP. Further documentation, including donor information, will be maintained by the individual blood collection facilities and not by ABC or BCA.

J. Support and coordination of delivery of convalescent plasma units for use in the Expanded Access Protocol and other federally funded COVID19 efforts as directed by BARDA.

1. Collect and deliver (b)(4) of convalescent plasma to hospitals and medical centers participating in the Expanded Access Protocol administered by the Mayo Clinic.
2. Collect and deliver (b)(4) of convalescent plasma to Grifols for use in manufacturing hyperimmune globulin products (b)(4) (b)(4) over a time frame to be determined and agreed upon by BARDA and ABC. Activity should be initiated no later than May 25, provided (b)(4) has shared their specifications and such specifications have been mutually agreed to by May 18th.
3. Collect and deliver (b)(4) of convalescent plasma to (b)(4) for use in manufacturing hyperimmune globulin products (b)(4) (b)(4) over a time frame to be determined and agreed upon by BARDA and ABC. Activity should be initiated no later than May 25.

K. Coordination of additional CCP units of plasma retention samples for other investigational use

ABC will assist in the provision of CCP units and plasma retention samples as needed by BARDA for use in investigational studies outside the scope of this contract. These units/samples will be provided assuming availability.

L. Options

Unless the Government exercises its option pursuant to the Option Clause set forth in Attachment 4 – Special Contracting Requirements, the contract will consist only of the Contract Line Items (CLINs) 1 – 5. Pursuant to that Option Clause, the Government may, by unilateral contract modification, require the Contractor to perform the additional options set forth below. If the Government exercises an option, written notice must be given at least 3 days prior to exercising the option, and the price of the contract will be increased as set forth in Standard Form 30 of Modification 1.

The following options are outlined in the table below:

1. Collect and deliver (b)(4) of convalescent plasma to hospitals and medical centers participating in the Expanded Access Protocol administered by the Mayo Clinic.

2. Collect and deliver (b)(4) of convalescent plasma to hospitals and medical centers participating in the Expanded Access Protocol administered by the Mayo Clinic. (repeatable (b)(4))
3. Collect and deliver (b)(4) of convalescent plasma to hospitals and medical centers participating in the Expanded Access Protocol administered by the Mayo Clinic. (repeatable (b)(4))
4. Collect and deliver (b)(4) of convalescent plasma to hospitals and medical centers participating in the Expanded Access Protocol administered by the Mayo Clinic. (repeatable (b)(4))
5. Collect and deliver (b)(4) of convalescent plasma to (b)(4) for use in manufacturing hyperimmune globulin products (b)(4) over a time frame to be determined and agreed upon by BARDA and ABC. Initiation of activity to be determined. (Repeatable (b)(4))
6. Collect and deliver (b)(4) of convalescent plasma to Emergent for use in manufacturing hyperimmune globulin products (b)(4) (b)(4) over a time frame to be determined and agreed upon by BARDA and ABC. Initiation of activity to be determined. (Repeatable (b)(4))
7. Collect and deliver (b)(4) of pathogen reduced convalescent plasma for use in a randomized clinical trial funded by the National Heart, Lung, and Blood Institute at the National Institutes of Health entitled "Clinical-trial of COVID-19 Convalescent Plasma in Outpatients (C3PO)" and executed by is the "Strategies to Innovate EmERgENcy Care Clinical Trials Network (SIREN)".
8. Shipping for units to testing facility and titer testing using an neutralizing antibody test for up to (b)(4) (repeatable (b)(4))

ATTACHMENT 2 – CONTRACT ADMINISTRATION**A. CONTRACTING OFFICER**

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

Jeffrey Schmidt, Jeffrey.schmidt2@hhs.gov

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.

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

No information other than that which may be contained in an authorized modification to this Contract, duly issued by the CO, which may be received from any person employed by the Government, or otherwise, shall be considered grounds for deviation from any stipulation of this Contract.

The Government may unilaterally change its CO designation, after which it will notify the Contractor in writing of such change.

B. CONTRACTING OFFICER'S REPRESENTATIVE

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

Beryl Voigt, Beryl.Voigt@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 Contracting Officer changes in requirements; (2) 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 Contracting Officer is the only person with authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the statement of work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor for any costs incurred during the performance of this contract; (5) otherwise change any terms and conditions of this contract; or (6) sign written licensing agreements. Any signed agreement shall be incorporated by reference in Section K of the contract

The Government may unilaterally change its COR designation.

C. INVOICING

Contractor may invoice weekly or on a per unit basis following shipment of that unit for eligible units distributed under this contract. Invoice instructions for firm fixed price contracts are attached and made part of this contract. The Contractor must follow the attached instructions to meet the requirements of a "proper invoice" pursuant to FAR Subpart 32.9, Prompt Payment. A "proper invoice" is defined as an invoice using a format approved by BARDA.

D. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE**1. Contractor Performance Evaluations**

A final evaluation of Contractor performance will be prepared on this contract in accordance with FAR Subpart 42.15 at the time of completion of work.

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

A copy of the evaluation, Contractor response, and review comments, if any, will be retained as part of the contract file, and may be used to support future award decisions.

2. Electronic Access to Contractor Performance Evaluations

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

E. ACCEPTANCE

Units will be deemed accepted by the Government upon shipment to their delivery destination. Units that meet the requirements of this agreement will be deemed accepted by the Government upon shipment to their delivery destination. Units that are damaged in transit are not eligible for reimbursement. The Contractor is not responsible for issues relating to the collection of the units by the blood collection facilities or the quality of the units collected.

F. PAYMENT

The Government will approve invoices for payment within 3 business days after submission of a proper invoice. Payment is due 30 days after submission of a proper invoice.

G. PARTICIPANTS AND SUBCONTRACTORS

1. The blood collection facilities supplying product are acting under Participant Agreements with BCA.
2. ABC will undertake efforts, in good faith, to (b)(4) to the terms and conditions required to be included in commercial item subcontracts and any other

terms required by this contract. It is understood, however, that ABC (b)(4)

(b)(4)

ATTACHMENT 3 – REPORTING AND MEETINGS REQUIREMENTS

The items specified below are required to be delivered F.o.b. Destination as set forth in FAR Clause 52.247-29, F.o.b. ORIGIN (Feb 2006), and in accordance with and by the date(s) specified below:

Item	Deliverable	Delivery Method	Due Date
1	Post Award Teleconference	Electronically to CO & COR	<p>Within one week of contract award.</p> <p>Contractor shall provide agenda and establish a teleconference number at least 3 business days in advance of the teleconference unless notified that BARDA will supply one.</p> <p>COR edits/approves and instructs contractor to distribute agenda prior to meeting by at least 2 business days.</p> <p>Contractor provides meeting minutes to COR within 3 business days after the meeting.</p> <p>COR reviews, comments and approves minutes within 10 business days.</p>
2	FDA Meetings	Electronically to CO & COR	<p>Contractor shall notify BARDA of upcoming FDA meeting related to the scope of this contract within 24 hours of scheduling meetings OR within 24 hours of meeting occurrence for ad hoc meetings, provided Contractor has advanced notice of such meetings.</p> <p>The Contractor shall forward initial Contractor and FDA-issued draft minutes and final minutes of any meeting, if any, with the FDA to BARDA within 2 business days of receipt.</p>
3	Twice Weekly Check-in With Project Staff	Electronically to CO & COR	<p>No agenda will be required for the meeting.</p> <p>No meeting minutes are required.</p>

			Contractor will provide bulleted email updates following any call or in lieu of a call by 2PM for that day.
4	Weekly Progress Reports	Electronically to CO & COR	<p>Weekly Reports shall be submitted on Mondays, covering the preceding week.</p> <p>The report shall include (1) the number of units collected by week, the number of units distributed by week (indicating where the units were sent (i.e., Mayo, EAP, NIH/NHLBI randomized clinical trial, Hyperimmune globulin manufacturing)); (2) number of units collected by month, the number of units distributed by month (indicating where the units were sent (i.e., Mayo, EAP, NIH/NHLBI randomized clinical trial, Hyperimmune globulin manufacturing)); (3) and the production forecast for the following month.</p>
5	Draft and Final Progress Reports	Electronically to CO & COR	<p>The Draft Technical Progress Report shall be submitted 15 calendar days before the end of the PoP and the Final Technical Progress Report on or before the completion date of the PoP.</p> <p>COR will provide feedback on draft report within 7 calendar days of receipt, which the Contractor shall consider incorporating into the Final Report.</p>
6	Final Data Submission Package	Electronically to CO & COR	Contractor must submit a data package consisting of all raw data produced under this contract. Data may be used by BARDA for analysis, evaluation, shared with other agencies, or shared outside of the

			<p>government consistent with FAR 52.227-14. This submission package must be delivered in a non-proprietary format. If clinical trial data are included, that data must be provided consistent with applicable privacy laws to protect personally identifiable information (PII).</p> <p>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.</p>
7	Incident Report	Electronically to CO & COR	<p>Contractor shall communicate to BARDA and document all critical programmatic concerns, issues, or probable risks that have or are likely to significantly impact project schedule and/or cost and/or performance. "Significant" is frequently defined as a 10% or greater cost or schedule variance within a control account, but should be confirmed in consultation with the COR. Incidents that present liability to the project even without cost/schedule impact, such as breach of GCP during a clinical study, must also be reported.</p> <p>Due within 48 hours of activity or incident or within 24 hours for a security activity or incident.</p> <p>Email or telephone with written follow-up to COR and CO.</p> <p>Additional updates due to COR and CO within 48 hours of additional developments.</p> <p>Contractor shall submit within 5 business days a Corrective Action Plan (if deemed necessary by either</p>

			<p>party) to address any potential issues.</p> <p>If corrective action is deemed necessary, Contractor must address in writing, its consideration of concerns raised by BARDA within 5 business days of receiving such concerns.</p>
8	FDA Correspondence	Electronically to CO & COR	Contractor shall provide copies of any FDA correspondence relating to the work performed by ABC under this contract within 2 business days of correspondence.

ATTACHMENT 4 – SPECIAL CONTRACT REQUIREMENTS**A. REPORTING MATTERS OF 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

B. ACKNOWLEDGEMENT 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 ten (10) 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. 75A50120C00094."

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, under Contract No. 75A50120C00094."

BARDA Use of Contractor Logo

Contractor hereby grants BARDA 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).

C. 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 (A) an alien lawfully admitted for permanent residence, or (B) authorized to be so employed by this Act or by the Attorney General."

D. NOTIFICATION OF CRITICAL PROGRAMMATIC CONCERNS, RISK, 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.

1. Within 48 hours of activity or incident or within 24 hours for a security related activity or incident, Contractor must notify BARDA.
2. Additional updates due to COR and CO within 48 hours of additional developments.
3. 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.

E. RETENTION SAMPLES

Reimbursement for a unit of plasma will only be provided if a retention sample has been collected.

F. START-UP COSTS

Reimbursement will only be provided for start-up costs reported to BARDA prior to May 5.

G. FAR CLAUSE 5.217-7, OPTION FOR INCREASED QUANTITY-SEPARATELY PRICED LINE ITEM (MARCH 1989)

The Government may require the delivery of the numbered line item, identified in the Schedule as an option item, in the quantity and at the price stated in the Schedule. The Contracting Officer may exercise the option by written notice to the Contractor at any point during contract performance. Delivery of added items shall continue at the same rate that like items are called for under the contract, unless the parties otherwise agree.

(End of Clause)

H. FAR CLAUSES INCORPORATED BY REFERENCE

This contract incorporates the following clauses and provisions 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 text of a clause may be accessed electronically:

FAR Clauses at: <http://www.acquisition.gov/far/>

1. FAR Provision **52.204-24 Representation Regarding Certain Telecommunications and Video Surveillance Services or Equipment** (Dec 2019).
2. FAR Clause **52.222-26 Equal Opportunity** (Sept 2016).

Notice: The following terms of this clause are waived for this contract: subparagraph (c)(2), (c)(3), (c)(4), (c)(5)(ii), (c)(6), (c)(8), and the phrase “on-site compliance evaluations and” in (c)(9).

3. FAR Clause **52.222-35 Equal Opportunity for Veterans** (Oct 2015).

Notice: The following terms of this clause are waived for this contract: in subparagraph (b), the phrase “and requires affirmative action by the Contractor to employ and advance in employment qualified protected veterans”; additionally, in subparagraph (b), the phrase “requirements of the equal opportunity clause at 41 CFR 60-300.5(a)” shall be interpreted to exclude in full paragraphs 2-7, 9-10, and 12 of 41 CFR 60-300.5(a), and the phrase “take affirmative action to employ, advance in employment and otherwise” from paragraph 1 of 41 CFR 60-300.5(a).

4. FAR Clause **52.222-36 Equal Opportunity for Workers with Disabilities** (Jul 2014).

Notice: The following terms of this clause are waived for this contract: in subparagraph (a), the phrase “and requires affirmative action by the Contractor to employ and

advance in employment qualified individuals with disabilities”; additionally, in subparagraph (a), the phrase “requirements of the equal opportunity clause at 41 CFR 60-741.5(a)” shall be interpreted to exclude in full paragraphs 4-5 and 7 of 41 CFR 60-741.5(a), and the phrase “take affirmative action to employ and advance in employment individuals with disabilities, and to” from paragraph 1 of 41 CFR 60-741.5(a).

FAR 52.212-4 Terms and Conditions – Commercial Items is incorporated by reference. The below addendum is incorporated by attachment.

(s) *Order of precedence.* Any inconsistencies in this solicitation or contract shall be resolved by giving precedence in the following order:

- (1) The schedule of supplies/services
- (2) The Assignments, Disputes, Payments [except for specific payment terms in this contract], Invoice, Other Compliances, Compliance with Laws Unique to Government Contracts, Unauthorized Obligations, and Commercial Supplier Agreements – Unenforceable Clauses paragraphs of this clause.
- (3) Attachment 4, Section H. FAR Clauses Incorporated by Reference
- (4) The clause at 52.212-5.
- (5) Addenda to this solicitation or contract, including any commercial supplier agreements as amended by the Commercial Supplier Agreements – Unenforceable Clauses provision.
- (6) Solicitation provisions if this is a solicitation.
- (7) Other paragraphs of this clause.
- (8) The Standard Form 1449.
- (9) Other documents, exhibits, and attachments.
- (10) The specification.

(t) *Commercial supplier agreements–unenforceable clauses.*

(1) Definition. For the purpose of this contract, “Commercial supplier agreements” (referred to at FAR 12.216 as “Supplier License Agreements”) means terms and conditions customarily offered to the public by vendors of supplies or services that meet the definition of “commercial item” set forth in FAR 2.101 and intended to create a binding legal obligation on the end user. Commercial supplier agreements are particularly common in information technology acquisitions, including acquisitions of commercial computer software and commercial technical data, but they may apply to any supply or service. The term applies–

(a) Regardless of the format or style of the document. For example, a commercial supplier agreement may be styled as standard terms of sale or lease, Terms of Service (TOS), End User License Agreement (EULA), or another similar legal instrument or agreement, and may be presented as part of a proposal or quotation responding to a solicitation for a contract or order;

(b) Regardless of the media or delivery mechanism used. For example, a commercial supplier agreement may be presented as one or more paper documents or may appear on a computer or other electronic device screen during a purchase, software installation, other product delivery, registration for a service, or another transaction.

(2) When any supply or service acquired under this contract is subject to a commercial supplier agreement, and notwithstanding any other provision of this agreement, when the end user is an agency or instrumentality of the U.S. Government, the following language shall be deemed incorporated into the commercial supplier agreement. As used herein, “this agreement” means the commercial supplier agreement.

(i) *Applicability.* This agreement is a part of a contract between the commercial supplier and the U.S. Government for the acquisition of the supply or service that necessitates a license or other similar legal instrument (including all contracts, task orders, and delivery orders under FAR Part 12).

(ii) *End user.* This agreement shall bind the ordering activity as end user but shall not operate to bind a Government employee or person acting on behalf of the Government in his or her personal capacity.

(iii) *Law and disputes.* This agreement is governed by Federal law.

(A) Any language purporting to subject the U.S. Government to the laws of a U.S. state, U.S. territory, district, or municipality, or a foreign nation, except where Federal law expressly provides for the application of such laws, is hereby deleted.

(B) Any language requiring dispute resolution in a specific forum or venue that is different from that prescribed by applicable Federal law is hereby deleted.

(C) Any language prescribing a different time period for bringing an action than that prescribed by applicable Federal law in relation to a dispute is hereby deleted.

(iv) *Continued performance.* The supplier or licensor shall not unilaterally revoke, terminate or suspend any rights granted to the Government except as allowed by this contract. If the supplier or licensor believes the ordering activity to be in breach of the agreement, it shall pursue its rights under the Contract Disputes Act or other applicable Federal statute while continuing performance as set forth in subparagraph 52.212-4(d) (Disputes).

(v) *Arbitration; equitable or injunctive relief.* In the event of a claim or dispute arising under or relating to this agreement, a binding arbitration shall not be used unless specifically authorized by agency guidance, and equitable or injunctive relief, including the award of attorney fees, costs or interest, may be awarded against the U.S. Government only when explicitly provided by statute (e.g., Prompt Payment Act or Equal Access to Justice Act).

(vi) Updating terms.

(A) After award, the contractor may unilaterally revise commercial supplier agreement terms if they are not material. A material change is defined as:

- (1) Terms that change Government rights or obligations;
- (2) Terms that increase Government prices;
- (3) Terms that decrease overall level of service; or
- (4) Terms that limit any other Government right addressed elsewhere in this contract.

(B) For revisions that will materially change the terms of the contract, the revised commercial supplier agreement must be incorporated into the contract using a bilateral modification.

(C) Any agreement terms or conditions unilaterally revised subsequent to award that are inconsistent with any material term or provision of this contract shall not be enforceable against the Government, and the Government shall not be deemed to have consented to them.

(vii) *No automatic renewals.* If any license or service tied to periodic payment is provided under this agreement (e.g., annual software maintenance or annual lease term), such license or service shall not renew automatically upon expiration of its current term without prior express consent by an authorized Government representative.

(viii) *Indemnification.* Any clause of this agreement requiring the commercial supplier or licensor to defend or indemnify the end user is hereby amended to provide that the U.S. Department of Justice has the sole right to represent the United States in any such action, in accordance with 28 U.S.C. 516.

(ix) *Audits.* Any clause of this agreement permitting the commercial supplier or licensor to audit the end user's compliance with this agreement is hereby amended as follows:

(A) Discrepancies found in an audit may result in a charge by the commercial supplier or licensor to the ordering activity. Any resulting invoice must comply with the proper invoicing requirements specified in the underlying Government contract or order.

(B) This charge, if disputed by the ordering activity, will be resolved in accordance with subparagraph (d) (Disputes); no payment obligation shall arise on the part of the ordering activity until the conclusion of the dispute process.

(C) Any audit requested by the contractor will be performed at the contractor's expense, without reimbursement by the Government.

(x) *Taxes or surcharges.* Any taxes or surcharges which the commercial supplier or licensor seeks to pass along to the Government as end user will be governed by the terms of the underlying Government contract or order and, in any event, must be submitted to the Contracting Officer for a determination of applicability prior to invoicing unless specifically agreed to otherwise in the Government contract.

(xi) *Non-assignment.* This agreement may not be assigned, nor may any rights or obligations thereunder be delegated, without the Government's prior approval, except as expressly permitted under subparagraph (b) of this clause.

(xii) *Confidential information.* If this agreement includes a confidentiality clause, such clause is hereby amended to state that neither the agreement nor the contract price list, as applicable, shall be deemed “confidential information.” Issues regarding release of “unit pricing” will be resolved consistent with the Freedom of Information Act. Notwithstanding anything in this agreement to the contrary, the Government may retain any confidential information as required by law, regulation or its internal document retention procedures for legal, regulatory or compliance purposes; provided, however, that all such retained confidential information will continue to be subject to the confidentiality obligations of this agreement.

(3) If any language, provision, or clause of this agreement conflicts or is inconsistent with the preceding paragraph (1), the language, provisions, or clause of paragraph (1) shall prevail to the extent of such inconsistency.

(End of clause)

52.212-5 CONTRACT TERMS AND CONDITIONS REQUIRED TO IMPLEMENT STATUTES OR EXECUTIVE ORDERS—COMMERCIAL ITEMS (Aug 2019)

(a) The Contractor shall comply with the following Federal Acquisition Regulation (FAR) clauses, which are incorporated in this contract by reference, to implement provisions of law or Executive orders applicable to acquisitions of commercial items:

(1) 52.203-19, Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (Jan 2017) (section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions)).

(2) 52.204-23, Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities (Jul 2018) (Section 1634 of Pub. L. 115-91).

(3) 52.204-25, Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment. (Aug 2019) (Section 889(a)(1)(A) of Pub. L. 115-232).

(4) 52.209-10, Prohibition on Contracting with Inverted Domestic Corporations (Nov 2015).

(5) 52.233-3, Protest After Award (Aug 1996) (31 U.S.C. 3553).

(6) 52.233-4, Applicable Law for Breach of Contract Claim (Oct 2004) (Public Laws 108-77 and 108-78 (19 U.S.C. 3805 note)).

(b) The Contractor shall comply with the FAR clauses in this paragraph (b) that the Contracting Officer has indicated as being incorporated in this contract by reference to implement provisions of law or Executive orders applicable to acquisitions of commercial items:

[Contracting officer check as appropriate.]

- | | | | |
|-------------------------------------|------|-----------|--|
| <input checked="" type="checkbox"/> | (1) | 52.203-6 | Restrictions on Subcontractor Sales to the Government (Sept 2006), with Alternate I (Oct 1995) (41 U.S.C. 4704 and 10 U.S.C. 2402). |
| <input checked="" type="checkbox"/> | (2) | 52.203-13 | Contractor Code of Business Ethics and Conduct (Oct 2015) (41 U.S.C. 3509)). |
| <input type="checkbox"/> | (3) | 52.203-15 | Whistleblower Protections under the American Recovery and Reinvestment Act of 2009 (June 2010) (Section 1553 of Pub. L. 111-5). (Applies to contracts funded by the American Recovery and Reinvestment Act of 2009.) |
| <input checked="" type="checkbox"/> | (4) | 52.204-10 | Reporting Executive Compensation and First-Tier Subcontract Awards (Oct 2018) (Pub. L. 109-282) (31 U.S.C. 6101 note). |
| | (5) | | [Reserved]. |
| <input type="checkbox"/> | (6) | 52.204-14 | Service Contract Reporting Requirements (Oct 2016) (Pub. L. 111-117, section 743 of Div. C). |
| <input type="checkbox"/> | (7) | 52.204-15 | Service Contract Reporting Requirements for Indefinite-Delivery Contracts (Oct 2016) (Pub. L. 111-117, section 743 of Div. C). |
| <input type="checkbox"/> | (8) | 52.209-6 | Protecting the Government's Interest When Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment. (Oct 2015) (31 U.S.C. 6101 note). |
| <input type="checkbox"/> | (9) | 52.209-9 | Updates of Publicly Available Information Regarding Responsibility Matters (Oct 2018) (41 U.S.C. 2313). |
| | (10) | | [Reserved]. |
| <input type="checkbox"/> | (11) | 52.219-3 | Notice of HUBZone Set-Aside or Sole-Source Award (Nov 2011) (15 U.S.C.657a). |
| <input type="checkbox"/> | | | (ii) Alternate I (Nov 2011) of 52.219-3. |

- (12) 52.219-4 (i), Notice of Price Evaluation Preference for HUBZone Small Business Concerns (OCT 2014) (if the offeror elects to waive the preference, it shall so indicate in its offer) (15 U.S.C. 657a).
 (ii) Alternate I (JAN 2011) of 52.219-4.
- (13) [Reserved].
- (14) 52.219-6 (i) Notice of Total Small Business Set-Aside (Nov 2011) (15 U.S.C. 644).
 (ii) Alternate I (Nov 2011).
 (iii) Alternate II (Nov 2011).
- (15) 52.219-7 (i) 52.219-7, Notice of Partial Small Business Set-Aside (June 2003) (15 U.S.C. 644).
 (ii) Alternate I (Oct 1995) of 52.219-7.
 (iii) Alternate II (Mar 2004) of 52.219-7.
- (16) 52.219-13 Utilization of Small Business Concerns (Oct 2018) (15 U.S.C. 637(d)(2) and (3)).
- (17) 52.219-9 (i), Small Business Subcontracting Plan (Aug 2018) (15 U.S.C. 637(d)(4)).
 (ii) Alternate I (Nov 2016) of 52.219-9.
 (iii) Alternate II (Nov 2016) of 52.219-9.
 (iv) Alternate III (Nov 2016) of 52.219-9.
 (v) Alternate IV (Aug 2018) of 52.219-9.
- (18) 52.219-13 Notice of Set-Aside of Orders (Nov 2011) (15 U.S.C. 644(r)).
- (19) 52.219-14 Limitations on Subcontracting (Jan 2017) (15 U.S.C. 637(a)(14)).
- (20) 52.219-16 Liquidated Damages—Subcontracting Plan (Jan 1999) (15 U.S.C. 637(d)(4)(F)(i)).
- (21) 52.219-27 Notice of Service-Disabled Veteran-Owned Small Business Set-Aside (Nov 2011) (15 U.S.C. 657 f).
- (22) 52.219-28 Post Award Small Business Program Rerepresentation (Jul 2013) (15 U.S.C. 632(a)(2)). May require contractor completion.
- (23) 52.219-29 Notice of Set-Aside for, or Sole Source Award to, Economically Disadvantaged Women-Owned Small Business Concerns (Dec 2015) (15 U.S.C. 637(m)).
- (24) 52.219-30 Notice of Set-Aside for, or Sole Source Award to, Women-Owned Small Business Concerns Eligible Under the Women-Owned Small Business Program (Dec 2015) (15 U.S.C. 637(m)).
- (25) 52.222-3 Convict Labor (June 2003) (E.O. 11755).
- (26) 52.222-19 Child Labor—Cooperation with Authorities and Remedies (Jan 2018) (E.O. 13126).
- (27) 52.222-21 Prohibition of Segregated Facilities (Apr 2015).

- (28) 52.222-26 (i) Equal Opportunity (Sept 2016) (E.O. 11246).
(ii) Alternate I (Feb 1999) of 52.222-26. Alt I requires CO completion.

If FAR 52.222-26 is included, then HHSAR 353.222-70, Contractor Cooperation in Equal Employment Opportunity Investigations is incorporated by reference.

- (29) 52.222-35 (i) Equal Opportunity for Veterans (Oct 2015)(38 U.S.C. 4212).
(ii) Alternate I (July 2014) of 52.222-35. Alt I requires CO completion.
- (30) 52.222-36 (i) Equal Opportunity for Workers with Disabilities (Jul 2014) (29 U.S.C. 793).
 (ii) Alternate I (July 2014) of 52.222-36. Alt I requires CO completion.
- (31) 52.222-37 Employment Reports on Veterans (FEB 2016) (38 U.S.C. 4212).
- (32) 52.222-40 Notification of Employee Rights Under the National Labor Relations Act (Dec 2010) (E.O. 13496).
- (33) 52.222-50 (i) Combating Trafficking in Persons (Jan 2019) (22 U.S.C. chapter 78 and E.O. 13627).
 (ii) Alternate I (Mar 2015) of 52.222-50 (22 U.S.C. chapter 78 and E.O. 13627). Alt I requires CO completion.
- (34) 52.222-54 Employment Eligibility Verification (OCT 2015). (Executive Order 12989). (Not applicable to the acquisition of commercially available off-the-shelf items or certain other types of commercial items as prescribed in 22.1803.)
- (35) 52.223-9 (i) Estimate of Percentage of Recovered Material Content for EPA–Designated Items (May 2008) (42 U.S.C. 6962(c)(3)(A)(ii)). (Not applicable to the acquisition of commercially available off-the-shelf items.) Requires CO completion.
 (ii) Alternate I (May 2008) of 52.223-9 (42 U.S.C. 6962(i)(2)(C)). (Not applicable to the acquisition of commercially available off-the-shelf items.) Alt I requires contractor certification.
- (36) 52.223-11 Ozone-Depleting Substances and High Global Warming Potential Hydrofluorocarbons (JUN 2016) (E.O. 13693). Requires contractor completion.
- (37) 52.223-12 Maintenance, Service, Repair, or Disposal of Refrigeration Equipment and Air Conditioners (JUN 2016) (E.O. 13693).
- (38) 52.223-13 (i), Acquisition of EPEAT®-Registered Imaging Equipment (JUN 2014) (E.O.s 13423 and 13514).
 (ii) Alternate I (Oct 2015) of 52.223-13.
- (39) 52.223-14 (i) Acquisition of EPEAT®-Registered Televisions (JUN 2014) (E.O.s 13423 and 13514).
 (ii) Alternate I (Jun 2014) of 52.223-14.
- (40) 52.223-15 Energy Efficiency in Energy-Consuming Products (DEC 2007) (42 U.S.C. 8259b).
- (41) 52.223-16 (i), Acquisition of EPEAT®-Registered Personal Computer Products (OCT 2015) (E.O.s 13423 and 13514).
 (ii) Alternate I (Jun 2014) of 52.223-16.
- (42) 52.223-18 Encouraging Contractor Policies to Ban Text Messaging While Driving (AUG 2011) (E.O. 13513).
- (43) 52.223-20 Aerosols (JUN 2016) (E.O. 13693).

- (44) 52.223-21 Foams (JUN 2016) (E.O. 13693).
- (45) 52.224-3 (i), Privacy Training (JAN 2017) (5 U.S.C. 552a).
- (ii) Alternate I (JAN 2017) of 52.224-3.
- (46) 52.225-1 Buy American—Supplies (May 2014) (41 U.S.C. chapter 83).
- (47) 52.225-3 (i), Buy American—Free Trade Agreements—Israeli Trade Act (May 2014) (41 U.S.C. chapter 83, 19 U.S.C. 3301 note, 19 U.S.C. 2112 note, 19 U.S.C. 3805 note, 19 U.S.C. 4001 note, Pub. L. 103-182, 108-77, 108-78, 108-286, 108-302, 109-53, 109-169, 109-283, 110-138, 112-41, 112-42, and 112-43.
- (ii) Alternate I (May 2014) of 52.225-3.
- (iii) Alternate II (May 2014) of 52.225-3.
- (iv) Alternate III (May 2014) of 52.225-3.
- (48) 52.225-5 Trade Agreements (AUG 2018) (19 U.S.C. 2501, et seq., 19 U.S.C. 3301 note).
- (49) 52.225-13 Restrictions on Certain Foreign Purchases (June 2008) (E.O.'s, proclamations, and statutes administered by the Office of Foreign Assets Control of the Department of the Treasury).
- (50) 52.225-26 Contractors Performing Private Security Functions Outside the United States (Oct 2016) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; 10 U.S.C. 2302 Note).
- (51) 52.226-4 Notice of Disaster or Emergency Area Set-Aside (Nov 2007) (42 U.S.C. 5150). Requires CO completion.
- (52) 52.226-5 Restrictions on Subcontracting Outside Disaster or Emergency Area (Nov 2007) (42 U.S.C. 5150).
- (53) 52.232-29 Terms for Financing of Purchases of Commercial Items (Feb 2002) (41 U.S.C. 4505, 10 U.S.C. 2307(f)).
- (54) 52.232-30 Installment Payments for Commercial Items (Jan 2017) (41 U.S.C. 4505, 10 U.S.C. 2307(f)).
- (55) 52.232-33 Payment by Electronic Funds Transfer—System for Award Management (Oct 2018) (31 U.S.C. 3332).
- (56) 52.232-34 Payment by Electronic Funds Transfer—Other than System for Award Management (Jul 2013) (31 U.S.C. 3332). Requires CO completion.
- (57) 52.232-36 Payment by Third Party (May 2014) (31 U.S.C. 3332).
- (58) 52.239-1 Privacy or Security Safeguards (Aug 1996) (5 U.S.C. 552a).
- (59) 52.242-5 Payments to Small Business Subcontractors (JAN 2017)(15 U.S.C. 637(d)(13)).
- (60) 52.247-64 (i), Preference for Privately Owned U.S.-Flag Commercial Vessels (Feb 2006) (46 U.S.C. Appx. 1241(b) and 10 U.S.C. 2631).
- (ii) Alternate I (Apr 2003) of 52.247-64.
- (iii) Alternate II (FEB 2006) of 52.247-64.

(c) The Contractor shall comply with the FAR clauses in this paragraph (c), applicable to commercial services, that the Contracting Officer has indicated as being incorporated in this contract by reference to implement provisions of law or Executive orders applicable to acquisitions of commercial items:

[Contracting Officer check as appropriate.]

- (1) 52.222-17 Nondisplacement of Qualified Workers (May 2014)(E.O. 13495).
- (2) 52.222-41 Service Contract Labor Standards (Aug 2018) (41 U.S.C. chapter 67).
- (3) 52.222-42 Statement of Equivalent Rates for Federal Hires (May 2014) (29 U.S.C. 206 and 41 U.S.C. chapter 67). Requires CO completion.
- (4) 52.222-43 Fair Labor Standards Act and Service Contract Labor Standards-Price Adjustment (Multiple Year and Option Contracts) (Aug 2018) (29 U.S.C. 206 and 41 U.S.C. chapter 67).
- (5) 52.222-44 Fair Labor Standards Act and Service Contract Labor Standards—Price Adjustment (May 2014) (29 U.S.C. 206 and 41 U.S.C. chapter 67).
- (6) 52.222-51 Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment—Requirements (May 2014) (41 U.S.C. chapter 67).
- (7) 52.222-53 Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services—Requirements (May 2014) (41 U.S.C. chapter 67).
- (8) 52.222-55 Minimum Wages Under Executive Order 13658 (Dec 2015).
- (9) 52.222-62 Paid Sick Leave Under Executive Order 13706 (JAN 2017) (E.O. 13706).
- (10) 52.226-6 Promoting Excess Food Donation to Nonprofit Organizations (May 2014) (42 U.S.C. 1792).

(d) Comptroller General Examination of Record. The Contractor shall comply with the provisions of this paragraph (d) if this contract was awarded using other than sealed bid, is in excess of the simplified acquisition threshold, and does not contain the clause at 52.215-2, Audit and Records—Negotiation.

(1) The Comptroller General of the United States, or an authorized representative of the Comptroller General, shall have access to and right to examine any of the Contractor's directly pertinent records involving transactions related to this contract.

(2) The Contractor shall make available at its offices at all reasonable times the records, materials, and other evidence for examination, audit, or reproduction, until 3 years after final payment under this contract or for any shorter period specified in FAR subpart 4.7, Contractor Records Retention, of the other clauses of this contract. If this contract is completely or partially terminated, the records relating to the work terminated shall be made available for 3 years after any resulting final termination settlement. Records relating to appeals under the disputes clause or to litigation or the settlement of claims arising under or relating to this contract shall be made available until such appeals, litigation, or claims are finally resolved.

(3) As used in this clause, records include books, documents, accounting procedures and practices, and other data, regardless of type and regardless of form. This does not require the Contractor to create or maintain any record that the Contractor does not maintain in the ordinary course of business or pursuant to a provision of law.

(1) Notwithstanding the requirements of the clauses in paragraphs (a), (b), (c), and (d) of this clause, the Contractor is not required to flow down any FAR clause, other than those in this paragraph (e)(1) in a subcontract for commercial items. Unless otherwise indicated below, the extent of the flow down shall be as required by the clause-

- (i) 52.203-13, Contractor Code of Business Ethics and Conduct (Oct 2015) (41 U.S.C. 3509).
- (ii) 52.203-19, Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (Jan 2017) (section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions)).
- (iii) 52.204-23, Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities (Jul 2018) (Section 1634 of Pub. L. 115-91).
- (iv) 52.204-25, Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment. (Aug 2019) (Section 889(a)(1)(A) of Pub. L. 115-232).
- (v) 52.219-8, Utilization of Small Business Concerns (Oct 2018) (15 U.S.C.637(d)(2) and (3)), in all subcontracts that offer further subcontracting opportunities. If the subcontract (except subcontracts to small business concerns) exceeds \$700,000 (\$1.5 million for construction of any public facility), the subcontractor must include 52.219-8 in lower tier subcontracts that offer subcontracting opportunities.
- (vi) 52.222-17, Nondisplacement of Qualified Workers (May 2014) (E.O. 13495). Flow down required in accordance with paragraph (l) of FAR clause 52.222-17.
- (vii) 52.222-21, Prohibition of Segregated Facilities (Apr 2015).
- (viii) 52.222-26, Equal Opportunity (Sept 2015) (E.O.11246).
- (ix) 52.222-35, Equal Opportunity for Veterans (Oct 2015) (38 U.S.C.4212).
- (x) 52.222-36, Equal Opportunity for Workers with Disabilities (Jul 2014) (29 U.S.C.793).
- (xi) 52.222-37, Employment Reports on Veterans (Feb 2016) (38 U.S.C.4212)
- (xii) 52.222-40, Notification of Employee Rights Under the National Labor Relations Act (Dec 2010) (E.O. 13496). Flow down required in accordance with paragraph (f) of FAR clause 52.222-40.
- (xiii) 52.222-41, Service Contract Labor Standards (Aug 2018) (41 U.S.C. chapter 67).
- (xiv) (A) 52.222-50, Combating Trafficking in Persons (Jan 2019) (22 U.S.C. chapter 78 and E.O 13627).
(B) Alternate I (Mar 2015) of 52.222-50(22 U.S.C. chapter 78 and E.O 13627).
- (xv) 52.222-51, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment-Requirements (May 2014) (41 U.S.C. chapter 67).
- (xvi) 52.222-53, Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services-Requirements (May 2014) (41 U.S.C. chapter 67).
- (xvii) 52.222-54, Employment Eligibility Verification (Oct 2015) (E.O. 12989).
- (xviii) 52.222-55, Minimum Wages Under Executive Order 13658 (Dec 2015).
- (xix) 52.222-62, Paid Sick Leave Under Executive Order 13706 (Jan 2017) (E.O. 13706).
- (xx) (A) 52.224-3, Privacy Training (Jan 2017) (5 U.S.C. 552a).
(B) Alternate I (Jan 2017) of 52.224-3.
- (xxi) 52.225-26, Contractors Performing Private Security Functions Outside the United States (Oct 2016) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; 10 U.S.C. 2302 Note).
- (xxii) 52.226-6, Promoting Excess Food Donation to Nonprofit Organizations (May 2014) (42 U.S.C. 1792). Flow down required in accordance with paragraph (e) of FAR clause 52.226-6.
- (xxiii) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (Feb 2006) (46 U.S.C. Appx.1241(b) and 10 U.S.C.2631). Flow down required in accordance with paragraph (d) of FAR clause 52.247-64.

(2) While not required, the Contractor may include in its subcontracts for commercial items a minimal number of additional clauses necessary to satisfy its contractual obligations.

(End of clause)

BARDA FIXED PRICE INVOICE INSTRUCTIONS

(a) Invoice Submission.

- (1) The Contractor shall submit invoices once per week.
- (2) A proper invoice, shall be sent electronically, via email, to the Program Officer, Contracting Officer and PSC mailboxes below:
 - (i) Program Officer, Beryl Voigt, Beryl.Voigt@hhs.gov
 - (ii) Contracting Officer, Jeffrey Schmidt, Jeffrey.Schmidt@hhs.gov
 - (iii) [PSC Invoices@psc.hhs.gov](mailto:PSC_Invoices@psc.hhs.gov)
- (3) The subject line of your email invoice submission shall contain the contract number, order number (if applicable), and the number of invoices. The Contractor shall send one email per contract per month. The email may have multiple invoices for the contract. Invoices must be in the following formats: PDF, TIFF, or Word. No Excel formats will be accepted. The electronic file cannot contain multiple invoices; example, 10 invoices requires 10 separate files (PDF or TIFF or Word).
- (4) Invoices shall be submitted in accordance with the contract terms, i.e. payment schedule, progress payments, partial payments, deliverables, etc.
- (5) All calls concerning contract payment shall be directed to the Program Officer.
- (6) Invoices will be handled in accordance with the Prompt Payment Act (31 U.S.C. 3903) and Office of Management and Budget (OMB) prompt payment regulations at 5 CFR Part 1315.

(b) Invoice Elements.

- (1) The Contractor shall submit an electronic invoice to the email addresses designated above. A proper invoice must include the following items:
 - (i) Name and address of the Contractor;
 - (ii) Invoice date and number;
 - (iii) Contract number, contract line item number and, if applicable, the order number;
 - (iv) Description, quantity, unit of measure, unit price and extended price of the items delivered;
 - (v) Shipping number and date of shipment, including the bill of lading number and weight of shipment if shipped on Government bill of lading;
 - (vi) Terms of any discount for prompt payment offered;
 - (vii) Name and address of official to whom payment is to be sent;
 - (viii) Name, title, and phone number of person to notify in event of defective invoice; and
 - (ix) Taxpayer Identification Number (TIN). The Contractor shall include its TIN on the invoice only if required elsewhere in this contract.
 - (x) Electronic funds transfer (EFT) banking information.
 - (A) The Contractor shall include EFT banking information on the invoice.
 - (B) In accordance with the requirements of the Debt Collection Improvement Act of 1996, all payments under this order will be made by electronic funds transfer (EFT). The Contractor shall provide financial institution information to the Finance Office designated above in accordance with FAR 52.232-33 Payment by Electronic Funds Transfer - System for Award Management.
- (2) Additionally, the Program Support Center (PSC) requires:

- (i) the invoice to break-out price/cost by contract line item number (CLIN) as specified in the pricing section of the contract
- (ii) the invoice to include the Dun & Bradstreet Number (DUNS) of the Contract

2. AMENDMENT/MODIFICATION NO. P00002	3. EFFECTIVE DATE See Block 16C	4. REQUISITION/PURCHASE REQ. NO. OS258838	5. PROJECT NO. (If applicable)
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6. ISSUED BY ASPR-BARDA 200 Independence Ave., S.W. Room 640-G Washington DC 20201	7. ADMINISTERED BY (If other than Item 6) ASPR-BARDA US DEPT OF HEALTH & HUMAN SERVICES BIOMEDICAL ADVANCED RESEACH & DEVELOPMENT AUT 200 INDEPENDENCE AVE, S.W. Washington DC 20201
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8. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and ZIP Code) AMERICA'S BLOOD CENTERS 1559070 725 15TH ST NW STE 700 WASHINGTON DC 200052109	9A. AMENDMENT OF SOLICITATION NO. 9B. DATED (SEE ITEM 11) 10A. MODIFICATION OF CONTRACT/ORDER NO. 75A50120C00094 10B. DATED (SEE ITEM 13) 04/17/2020
CODE 1559070 FACILITY CODE	

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers is extended. is not extended. Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or electronic communication which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by letter or electronic communication, provided each letter or electronic communication makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required) 2020.199C002.25103	Net Increase:	\$8,415,000.00
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13. THIS ITEM ONLY APPLIES TO MODIFICATION OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

CHECK ONE	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation data, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
X	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: FAR 52.217-7, OPTION FOR INCREASED QUANTITY-SEPARATELY PRICED LINE ITEM (MARCH 1989)
	D. OTHER (Specify type of modification and authority)

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

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)
 Tax ID Number: 86-6052376
 DUNS Number: 194910121
 The purpose of this modification is to exercise Option 1 - CLIN 6.

ALL OTHER TERMS AND CONDITIONS REMAIN UNCHANGED.
 Appr. Yr.: 2020 CAN: 199C002 Object Class: 25103
 Period of Performance: 04/17/2020 to 04/16/2021

Change Item 6 to read as follows (amount shown is the obligated amount):

Continued ...

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

15A. NAME AND TITLE OF SIGNER (Type or print)	16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) JEFFREY R. SCHMIDT
15B. CONTRACTOR/OFFEROR	16B. UNITED STATES OF AMERICA Jeffrey R. Schmidt -S <small>Digitally signed by Jeffrey R. Schmidt -S Date: 2020.05.21 10:06:54 -04'00'</small>
(Signature of person authorized to sign)	(Signature of Contracting Officer)
15C. DATE SIGNED	16C. DATE SIGNED 05/21/2020

CONTINUATION SHEET

REFERENCE NO. OF DOCUMENT BEING CONTINUED
75A50120C00094/P00002

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NAME OF OFFEROR OR CONTRACTOR
AMERICA'S BLOOD CENTERS 1559070

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
6	Option 1 (exercised): Collect and deliver (b)(4) (h)(4) of convalescent plasma to hospitals and medical centers participating in the Expanded Access Protocol administered by the Mayo Clinic. Obligated Amount: \$8,415,000.00				8,415,000.00

2. AMENDMENT/MODIFICATION NO. P00003	3. EFFECTIVE DATE See Block 16C	4. REQUISITION/PURCHASE REQ. NO. OS260116	5. PROJECT NO. (If applicable)
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6. ISSUED BY ASPR-BARDA 200 Independence Ave., S.W. Room 640-G Washington DC 20201	7. ADMINISTERED BY (If other than Item 6) ASPR-BARDA US DEPT OF HEALTH & HUMAN SERVICES BIOMEDICAL ADVANCED RESEARCH & DEVELOPMENT AUT 200 INDEPENDENCE AVE, S.W. Washington DC 20201
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8. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and ZIP Code) AMERICA'S BLOOD CENTERS 1559070 725 15TH ST NW STE 700 WASHINGTON DC 200052109	9A. AMENDMENT OF SOLICITATION NO. (x)
	9B. DATED (SEE ITEM 11)
	10A. MODIFICATION OF CONTRACT/ORDER NO. x 75A50120C00094
	10B. DATED (SEE ITEM 13) 04/17/2020

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers is extended. is not extended. Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or electronic communication which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by letter or electronic communication, provided each letter or electronic communication makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required) 2020.199C002.25103	Net Increase:	\$15,506,000.00
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13. THIS ITEM ONLY APPLIES TO MODIFICATION OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

CHECK ONE	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation data, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
X	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: FAR 52.217-7, OPTION FOR INCREASED QUANTITY-SEPARATELY PRICED LINE ITEM (MARCH 1989) and MUTUAL AGREEMENT
	D. OTHER (Specify type of modification and authority)

E. IMPORTANT: Contractor is not is required to sign this document and return 1 copies to the issuing office.

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

Tax ID Number: 86-6052376
DUNS Number: 194910121

The purpose of this modification is to (1) decrease the (b)(4) of convalescent plasma in Options 2, 3, and 4 from (b)(4); (2) exercise Option 3 (b)(4); (3) exercise Option 4 (b)(4); and (4) increase the repeatability of Option 2 - CLIN 7 (b)(4)

As a result of this modification, the Contractor shall collect and deliver (b)(4) of convalescent plasma to hospitals and medical centers participating in the Expanded Access Protocol administered by the Mayo Clinic (see CLIN 14) at a firm fixed price of (b)(4)

Continued ...

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

15A. NAME AND TITLE OF SIGNER (Type or print) Katherine Fry, Chief Executive Officer	16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) JEFFREY R. SCHMIDT
15B. CONTRACTOR/OFFEROR (b)(6) Katherine Fry <small>(Signature of person authorized to sign)</small>	15C. DATE SIGNED 6/9/2020
16B. UNITED STATES OF AMERICA Jeffrey R. Schmidt -S <small>(Signature of Contracting Officer)</small>	16C. DATE SIGNED Digitally signed by Jeffrey R. Schmidt -S Date: 2020.06.09 12:47:02 -04'00'

CONTINUATION SHEET

REFERENCE NO. OF DOCUMENT BEING CONTINUED
75A50120C00094/P00003

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NAME OF OFFEROR OR CONTRACTOR
AMERICA'S BLOOD CENTERS 1559070

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	<p>As a result of exercising Option 3 (b)(4) the repeatability of Option 3 - CLIN 8 is changed from (b)(4)</p> <p>As a result of exercising Option 4 (b)(4) the repeatability of Option 4 - CLIN 9 is changed from (b)(4)</p> <p>As a result of (b)(4) the repeatability of Option 2 by (b)(4) the total repeatability of Option 2 - CLIN 7 is (b)(4)</p> <p>ALL OTHER TERMS AND CONDITIONS REMAIN UNCHANGED.</p> <p>Appr. Yr.: 2020 CAN: 199C002 Object Class: 25103 Period of Performance: 04/17/2020 to 04/16/2021</p> <p>Change Item 7 to read as follows (amount shown is the obligated amount):</p>				
7	<p>Option 2: Collect and deliver (b)(4) of convalescent plasma to hospitals and medical centers participating in the Expanded Access Protocol administered by the Mayo Clinic (repeatability (b)(4)).</p> <p>Modification P00003 changed the repeatability from (b)(4) Amount: \$156,770,000.00 (Option Line Item)</p> <p>Change Item 8 to read as follows (amount shown is the obligated amount):</p>	(b)(4)	EA	(b)(4)	0.00
8	<p>Option 3: Collect and deliver (b)(4) of convalescent plasma to hospitals and medical centers participating in the Expanded Access Protocol administered by the Mayo Clinic (repeatability (b)(4)).</p> <p>Modification P00003 changed the repeatability from (b)(4) Amount: (b)(4) (Option Line Item)</p> <p>Change Item 9 to read as follows (amount shown is the obligated amount):</p>		EA		0.00
9	<p>Option 4: Collect and deliver (b)(4) of convalescent plasma to hospitals and medical centers participating in the Expanded Access Continued ...</p>		EA		0.00

CONTINUATION SHEET

REFERENCE NO. OF DOCUMENT BEING CONTINUED
75A50120C00094/P00003

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NAME OF OFFEROR OR CONTRACTOR
AMERICA'S BLOOD CENTERS 1559070

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
12	<p>Protocol administered by the Mayo Clinic (repeatable (b)(4)).</p> <p>Modification P00003 changed the repeatability from (b)(4). Amount: (b)(4) (Option Line Item)</p> <p>Change Item 12 to read as follows (amount shown is the obligated amount):</p> <p>Option 7: Collect and deliver (b)(4) pathogen reduced convalescent plasma for use in a randomized clinical trial funded by the National Heart, Lung, and Blood Institute at the National Institutes of Health entitled "Clinical-trial of COVID-19 Convalescent Plasma in Outpatients (C3PO)" and executed by is the "Strategies to Innovate EmergEncy Care Clinical Trials Network (SIREN)".</p> <p>EXERCISED Obligated Amount: (b)(4)</p> <p>Add Item 14 as follows:</p>				(b)(4)
14	<p>Collect and deliver (b)(4) of convalescent plasma to hospitals and medical centers participating in the Expanded Access Protocol administered by the Mayo Clinic.</p> <p>This contract line exercises Option 3 (b)(4) (b)(4) and Option 4 (b)(4) (b)(4). As a result, the quantity on Contract Line Item Number 8 is (b)(4) and the quantity on Contract Line Item Number 9 is (b)(4) (b)(4). Obligated Amount: (b)(4)</p>				

2. AMENDMENT/MODIFICATION NO. P00004	3. EFFECTIVE DATE See Block 16C	4. REQUISITION/PURCHASE REQ. NO. OS260872	5. PROJECT NO. (If applicable)
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6. ISSUED BY ASPR-BARDA 200 Independence Ave., S.W. Room 640-G Washington DC 20201	7. ADMINISTERED BY (If other than Item 6) ASPR-BARDA US DEPT OF HEALTH & HUMAN SERVICES BIOMEDICAL ADVANCED RESEARCH & DEVELOPMENT AUT 200 INDEPENDENCE AVE, S.W. Washington DC 20201
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8. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and ZIP Code) AMERICA'S BLOOD CENTERS 1559070 725 15TH ST NW STE 700 WASHINGTON DC 200052109	9A. AMENDMENT OF SOLICITATION NO. (x)
	9B. DATED (SEE ITEM 11)
	10A. MODIFICATION OF CONTRACT/ORDER NO. x 75A50120C00094
	10B. DATED (SEE ITEM 13) 04/17/2020

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers is extended. is not extended. Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or electronic communication which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by letter or electronic communication, provided each letter or electronic communication makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required) 2020.199C015.25103	Net Increase:	\$102,800,000.00
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13. THIS ITEM ONLY APPLIES TO MODIFICATION OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

CHECK ONE	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation data, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
X	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: FAR 52.217-7, OPTION FOR INCREASED QUANTITY-SEPARATELY PRICED LINE ITEM (MARCH 1989) and MUTUAL AGREEMENT
	D. OTHER (Specify type of modification and authority)

E. IMPORTANT: Contractor is not is required to sign this document and return 1 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)
 Tax ID Number: 86-6052376
 DUNS Number: 194910121
 The purpose of this modification is to (1) adjust the descriptions in CLINs 7, 8, and 9 to provide for needed flexibility; (2) exercise Option 2 (b)(4); (3) exercise Option 5 (b)(4); and (4) exercise Option 6 (b)(4)

As a result of this modification, the Contractor shall collect and distribute up to 200,000 additional units of convalescent plasma for use in the Expanded Access Protocol, HIG manufacturing, stockpiling, and other uses as directed by BARDA (see CLIN 15) at a firm fixed price of \$102,800,000.
 Continued ...

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

15A. NAME AND TITLE OF SIGNER (Type or print) Katherine Fry	16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) JEFFREY R. SCHMIDT
15B. CONTRACTOR/OFFEROR Katherine Fry (b)(6)	16B. UNITED STATES OF AMERICA Jeffrey R. Schmidt - S Digitally signed by Jeffrey R. Schmidt - S Date: 2020.06.22 15:38:12
15C. DATE SIGNED June 22, 2020	16C. DATE SIGNED June 22, 2020

NAME OF OFFEROR OR CONTRACTOR
AMERICA'S BLOOD CENTERS 1559070

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
7	<p>As a result of exercising Option 2 (b)(4) the repeatability of Option 2 - CLIN 7 is changed (b)(4)</p> <p>As a result of exercising Option 3 (b)(4) the repeatability of Option 3 - CLIN 8 is changed (b)(4)</p> <p>As a result of exercising Option 4 (b)(4) the repeatability of Option 4 - CLIN 9 is changed (b)(4)</p> <p>ALL OTHER TERMS AND CONDITIONS REMAIN UNCHANGED.</p> <p>Appr. Yr.: 2020 CAN: 199C015 Object Class: 25103 Period of Performance: 04/17/2020 to 04/16/2021</p> <p>Change Item 7 to read as follows (amount shown is the obligated amount):</p> <p>Option 2 (partially exercised): Collect and distribute (b)(4) of convalescent plasma for use in the Expanded Access Protocol, HIG manufacturing, stockpiling, and other uses as directed by BARDA (repeatability (b)(4)).</p> <p>Modification P00003 changed the repeatability (b)(4)</p> <p>Modification P00004: (1) changed the repeatability from (b)(4) and (2) adjusted the description to provide for needed flexibility. Amount: (b)(4) (Option Line Item)</p> <p>Change Item 8 to read as follows (amount shown is the obligated amount):</p>	(b)(4)	EA	(b)(4)	0.00
8	<p>Option 3 (exercised): Collect and distribute (b)(4) of convalescent plasma for use in the Expanded Access Protocol, HIG manufacturing, stockpiling, and other uses as directed by BARDA (b)(4).</p> <p>Modification P00003 changed the repeatability (b)(4)</p> <p>Modification P00004: (1) changed the repeatability (b)(4) and (2) Continued ...</p>	(b)(4)	EA	(b)(4)	0.00

CONTINUATION SHEET

REFERENCE NO. OF DOCUMENT BEING CONTINUED
75A50120C00094/P00004

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3 3

NAME OF OFFEROR OR CONTRACTOR
AMERICA'S BLOOD CENTERS 1559070

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
9	<p>adjusted the description to provide for needed flexibility. Amount: (b)(4)</p> <p>Change Item 9 to read as follows (amount shown is the obligated amount):</p> <p>Option 4 (exercised): Collection and distribute of (b)(4) of convalescent plasma for use in the Expanded Access Protocol, HIG manufacturing, stockpiling and other uses as directed by BARDA (fully exercised).</p> <p>Modification P00003 changed the repeatability (b)(4)</p> <p>Modification P00004: (1) changed the repeatability (b)(4) and (2) adjusted the description to provide for needed flexibility. Amount: (b)(4)</p> <p>Add Item 15 as follows:</p>	(b)(4)	EA	(b)(4)	0.00
15	<p>Collect and distribute up to (b)(4) (b)(4) of convalescent plasma for use in the Expanded Access Protocol, HIG manufacturing, stockpiling, and other uses as directed by BARDA.</p> <p>This contract line exercises Option 2 (b)(4) (b)(4), Option 3 (b)(4) (b)(4), Option 4 (b)(4) (b)(4). As a result, the quantity on Contract Line Number 7 is (b)(4) (b)(4) the quantity on Contract Line Number 8 is (b)(4) and the quantity on Contract Line Item Number 9 is (b)(4)</p> <p>Obligated Amount: (b)(4)</p>				(b)(4)

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT		1. CONTRACT ID CODE	PAGE OF PAGES 1 4
2. AMENDMENT/MODIFICATION NO. P00005	3. EFFECTIVE DATE See Block 16C	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. (If applicable)
6. ISSUED BY ASPR-BARDA 200 Independence Ave., S.W. Room 640-G Washington DC 20201	CODE ASPR-BARDA	7. ADMINISTERED BY (If other than Item 6) ASPR-BARDA US DEPT OF HEALTH & HUMAN SERVICES BIOMEDICAL ADVANCED RESEACH & DEVELOPMENT AUT 200 INDEPENDENCE AVE, S.W. Washington DC 20201	CODE ASPR-BARDA
8. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and ZIP Code) AMERICA'S BLOOD CENTERS 1559070 725 15TH ST NW STE 700 WASHINGTON DC 200052109		(x)	9A. AMENDMENT OF SOLICITATION NO.
CODE 1559070 FACILITY CODE			9B. DATED (SEE ITEM 11)
		x	10A. MODIFICATION OF CONTRACT/ORDER NO. 75A50120C00094
			10B. DATED (SEE ITEM 13) 04/17/2020

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers is extended. is not extended. Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or electronic communication which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by letter or electronic communication, provided each letter or electronic communication makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)

See Schedule

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

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

E. IMPORTANT: Contractor is not is required to sign this document and return 1 copies to the issuing office.

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

Tax ID Number: 86-6052376

DUNS Number: 194910121

The purpose of this modification is to: (1) correct the effective date of Modification P00003 to April 10, 2020; and (2) incorporate "Attachment 8 - Requirements for C3PO Doses" (2 pages) into the contract.

The following attachments are applicable to this order and incorporated by appendix:

8. Requirements for C3PO Doses.

ALL OTHER TERMS AND CONDITIONS REMAIN UNCHANGED.

Continued ...

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

15A. NAME AND TITLE OF SIGNER (Type or print) Katherine Fry	16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) JEFFREY R. SCHMIDT
15B. CONTRACTOR/OFFEROR Katherine Fry (b)(6) (Signature of person)	15C. DATE SIGNED 6/30/2020
16B. UNITED STATES OF AMERICA Digitally signed by Jeffrey R. Schmidt -S Date: 2020.06.30 17:05:10 -04'00' (Signature of Contracting Officer)	16C. DATE SIGNED 06/30/2020

Previous edition unusable

CONTINUATION SHEET

REFERENCE NO. OF DOCUMENT BEING CONTINUED
75A50120C00094/P00005

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2 4

NAME OF OFFEROR OR CONTRACTOR
AMERICA'S BLOOD CENTERS 1559070

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	Period of Performance: 04/17/2020 to 04/16/2021				

ATTACHMENT 8 – REQUIREMENTS FOR C3PO DOSES

Collect and deliver 500 doses of convalescent plasma for use in a randomized clinical trial funded by the National Heart, Lung, and Blood Institute at the National Institutes of Health entitled “Clinical-trial of COVID-19 Convalescent Plasma in Outpatients (C3PO)” and executed by is the “Strategies to Innovate EmeRgENcy Care Clinical Trials Network (SIREN)”.

The Contractor through a supplier will provide approximately 225 low-titer type-A units, approximately 225 type-O units, and approximately 50 units that are some combination of type-B and type-AB. The precise blood type will be mutually agreed upon by the Contractor or Supplier and the Government.

Prior to distribution of CCP to SIREN investigators, the Contractor through a supplier will determine binding SARS-CoV-2 antibody levels from the Ortho Vitros CoV2T assay, and SARS-CoV-2 neutralizing antibody titers from the reporter virus plaque neutralization assay (“RVPN”) or equivalent assays. Assay results will be provided to SIREN investigators electronically using a mutually agreed reporting format.

The Government will pay the Contractor for all units collected, selected, tested and prepared for distribution to SIREN investigators pursuant to this MOU, regardless of whether the units are transfused pursuant to the C3PO. The Government agrees all CCP distributed under this Option are non-returnable and non-refundable.

In the event C3PO clinical study terminates prior to distribution of the units, the Government will provide the Contractor with instructions within thirty (30) calendar days of termination of the study on where Sponsor would like the remaining inventory of units to be distributed.

SIREN will provide the shipping destination and required shipping specifications to the Contractor, and the shipping schedule will be mutually agreed upon by the Parties.

If requested by SIREN, the Contractor through a supplier will distribute one (1) aliquot of plasma for each CCP distributed to SIREN investigators for additional study or testing at SIREN’s designated centralized laboratory. The Contractor or supplier will not be responsible for any payment obligations for such additional studies or testing conducted at SIREN’s designated centralized laboratory.

Upon completion of RVPN testing, the Contractor may invoice the Government and be paid by the Government for each unit of CCP delivered to SIREN investigator.

The Government and the Contractor and its supplier understand and acknowledge that no laboratory tests or other procedures are presently available that can ensure that the CCP provided under this MOU are free from all agents, including but not limited to viruses and retroviruses, which may cause disease or illness, including but not limited to HIV, HTLV, Hepatitis. ACCORDINGLY, THE GOVERNMENT DOES NOT REQUIRE REPRESENTATIONS OR WARRANTIES OF ANY KIND, EITHER EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, WITH RESPECT TO THE CCP OR TESTING SERVICES PROVIDED UNDER THIS CONTRACT, INCLUDING WITHOUT LIMITATION ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

The Government considers the Contractor’s and its supplier’s participation and support for the C3PO are as “Covered Persons” to a medical “countermeasure” to combat COVID-19 under the Public Readiness and Preparedness Act (“PREP Act”), 42 USC 247d-6d and each Party will reasonably cooperate with the

Contract Number: 75A50120C00094
Modification Number: P00005

Attachment 8 – Requirements for C3PO Doses

other Party to secure any and all immunity and liability protections afforded under the PREP Act, the Coronavirus Aid, Relief, and Economic Security Act (“CARES Act”), or other applicable state or federal law.

2. AMENDMENT/MODIFICATION NO. P00006	3. EFFECTIVE DATE 07/13/2020	4. REQUISITION/PURCHASE REQ. NO. OS261538	5. PROJECT NO. (If applicable)
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6. ISSUED BY ASPR-BARDA 200 Independence Ave., S.W. Room 640-G Washington DC 20201	7. ADMINISTERED BY (If other than Item 6) ASPR-BARDA US DEPT OF HEALTH & HUMAN SERVICES BIOMEDICAL ADVANCED RESEACH & DEVELOPMENT AUT 200 INDEPENDENCE AVE, S.W. Washington DC 20201
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8. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and ZIP Code) AMERICA'S BLOOD CENTERS 1559070 725 15TH ST NW STE 700 WASHINGTON DC 200052109	9A. AMENDMENT OF SOLICITATION NO. 9B. DATED (SEE ITEM 11) 10A. MODIFICATION OF CONTRACT/ORDER NO. 75A50120C00094 10B. DATED (SEE ITEM 13) 04/17/2020
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11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers is extended. is not extended. Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or electronic communication which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by letter or electronic communication, provided each letter or electronic communication makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required) Net Increase: (b)(4)

2020.199C015.25103

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

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

E. IMPORTANT: Contractor is not is required to sign this document and return 1 copies to the issuing office.

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

Tax ID Number: 86-6052376
DUNS Number: 194910121

The purpose of this modification is to: (1) modify CLIN 15 to provide language to account for the possibility of an Emergency Use Authorization being granted for convalescent plasma; (2) add CLIN 16 to account for the surge activities that required to expedite the collection of units; and (3) add CLIN 17 to account for the advance purchase of collection kits/bags.

ALL OTHER TERMS AND CONDITIONS REMAIN UNCHANGED.

Appr. Yr.: 2020 CAN: 199C015 Object Class: 25103

Continued ...

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

15A. NAME AND TITLE OF SIGNER (Type or print) Katherine Fry, Chief Executive Officer	16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) JEFFREY R. SCHMIDT
15B. CONTRACTOR/OFFEROR Katherine Fry (b)(6)	16B. UNITED STATES OF AMERICA Jeffrey R. Schmidt -S
15C. DATE SIGNED 7/10/2020	16C. DATE SIGNED Digitally signed by Jeffrey R. Schmidt Date: 2020.07.13 08:41:34 -04'00'

NAME OF OFFEROR OR CONTRACTOR
AMERICA'S BLOOD CENTERS 1559070

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	<p>Period of Performance: 04/17/2020 to 04/16/2021</p> <p>Change Item 15 to read as follows (amount shown is the obligated amount):</p> <p>15 Collect and distribute up to 200,000 additional units of convalescent plasma for use in the Expanded Access Protocol, e-INDs, HIG manufacturing, stockpiling, and other uses as directed by BARDA.</p> <p>This contract line exercises Option 2 (b)(4) (b)(4), Option 3 (b)(4) (b)(4), Option 4 (b)(4) (b)(4). As a result, the quantity on Contract Line Number 7 is reduced (b)(4) the quantity on Contract Line Number 8 is (b)(4) and the quantity on Contract Line Item Number 9 is (b)(4)</p> <p>Modification P00006 adds the following language: If, under the performance of this option, an Emergency Use Authorization is granted for the use of convalescent plasma and there is a titer requirement threshold for use as convalescent plasma, it is agreed that some units may not meet the titer threshold. ABC will invoice (b)(4) for every unit that does not meet the titer threshold instead of the (b)(4). The unit prices under this contract line do not include surge pricing or cost for the purchase of collection kits/bags. Those prices are provided for under Contract Line Item Numbers 16 and 17. The Government and the Contractor agree that the price per unit that does not meet the titer threshold may be renegotiated during contract performance. The Government and the Contractor agree to conduct any renegotiations in good faith. Obligated Amount (b)(4)</p> <p>Add Item 16 as follows:</p>				0.00
16	<p>Ramp up collection activities to increase volume of convalescent plasma units collected - reflected in (b)(4) price (b)(4) Continued ...</p>				23,068,000.00

CONTINUATION SHEET

REFERENCE NO. OF DOCUMENT BEING CONTINUED
75A50120C00094/P00006

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3 3

NAME OF OFFEROR OR CONTRACTOR
AMERICA'S BLOOD CENTERS 1559070

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	<p>(b)(4) This surge pricing will cover up to (b)(4) plasma (b)(4) collected purchased under CLIN 15. Obligated Amount: \$23,068,000.00</p> <p>Add Item 17 as follows:</p>				
17	<p>Purchase of (b)(4) collections kits/bags at a unit price of (b)(4) for the plasma collected purchased under CLIN 14 (see Modification P00003) and CLIN 15 (see Modification P00004). Obligated Amount: \$21,000,000.00</p>				21,000,000.00

2. AMENDMENT/MODIFICATION NO. P00007	3. EFFECTIVE DATE See Block 16C	4. REQUISITION/PURCHASE REQ. NO. OS262683	5. PROJECT NO. (If applicable)
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6. ISSUED BY ASPR-BARDA 200 Independence Ave., S.W. Room 640-G Washington DC 20201	7. ADMINISTERED BY (If other than Item 6) ASPR-BARDA US DEPT OF HEALTH & HUMAN SERVICES BIOMEDICAL ADVANCED RESEACH & DEVELOPMENT AUT 200 INDEPENDENCE AVE, S.W. Washington DC 20201
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8. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and ZIP Code) AMERICA'S BLOOD CENTERS 1559070 725 15TH ST NW STE 700 WASHINGTON DC 200052109	9A. AMENDMENT OF SOLICITATION NO. 9B. DATED (SEE ITEM 11) 10A. MODIFICATION OF CONTRACT/ORDER NO. 75A50120C00094 10B. DATED (SEE ITEM 13) 04/17/2020
CODE 1559070 FACILITY CODE	

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers is extended. is not extended. Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or electronic communication which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by letter or electronic communication, provided each letter or electronic communication makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required) 2020.199C015.25103	Net Increase:	\$14,698,800.00
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13. THIS ITEM ONLY APPLIES TO MODIFICATION OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

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

E. IMPORTANT: Contractor is not is required to sign this document and return 1 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)
 Tax ID Number: 86-6052376
 DUNS Number: 194910121
 The purpose of this modification is to add CLIN 18 to account for surge activities that require expedited collection of convalescent plasma (b)(4)

ALL OTHER TERMS AND CONDITIONS REMAIN UNCHANGED.

Appr. Yr.: 2020 CAN: 199C015 Object Class: 25103
 Period of Performance: 04/17/2020 to 04/16/2021

Add Item 18 as follows:
 Continued ...

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

15A. NAME AND TITLE OF SIGNER (Type or print) Katherine Fry	16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) JEFFREY R. SCHMIDT
15B. CONTRACTOR/OFFEROR Katherine Fry (b)(6) <small>(Signature of person authorized to sign)</small>	15C. DATE SIGNED 7/28/20
16B. UNITED STATES OF AMERICA Jeffrey R. Schmidt -S Digitally signed by Jeffrey R. Schmidt -S Date: 2020.07.28 08:08:54 -04'00' <small>(Signature of Contracting Officer)</small>	16C. DATE SIGNED 7/28/20

CONTINUATION SHEET

REFERENCE NO. OF DOCUMENT BEING CONTINUED
75A50120C00094/P00007

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NAME OF OFFEROR OR CONTRACTOR
AMERICA'S BLOOD CENTERS 1559070

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
18	<p>Ramp up collection activities to increase volume of convalescent plasma (b)(4) collected - (b)(4)</p> <p>This (b)(4) will cover (b)(4) plasma (b)(4) collected under CLIN15. Obligated Amount: \$14,698,800.00</p>				14,698,800.00

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT		1. CONTRACT ID CODE	PAGE OF PAGES
			1 2
2. AMENDMENT/MODIFICATION NO. P00008	3. EFFECTIVE DATE See Block 16C	4. REQUISITION/PURCHASE REQ. NO. OS263438	5. PROJECT NO. (If applicable)
6. ISSUED BY ASPR-BARDA 200 Independence Ave., S.W. Room 640-G Washington DC 20201	CODE ASPR-BARDA	7. ADMINISTERED BY (If other than Item 6) ASPR-BARDA US DEPT OF HEALTH & HUMAN SERVICES BIOMEDICAL ADVANCED RESEACH & DEVELOPMENT AUT 200 INDEPENDENCE AVE, S.W. Washington DC 20201	CODE ASPR-BARDA
8. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and ZIP Code) AMERICA'S BLOOD CENTERS 1559070 725 15TH ST NW STE 700 WASHINGTON DC 200052109		(x)	9A. AMENDMENT OF SOLICITATION NO.
CODE 1559070 FACILITY CODE			9B. DATED (SEE ITEM 11)
		x	10A. MODIFICATION OF CONTRACT/ORDER NO. 75A50120C00094
			10B. DATED (SEE ITEM 13) 04/17/2020

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers is extended. is not extended. Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or electronic communication which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by letter or electronic communication, provided each letter or electronic communication makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required) Net Increase: \$425,000.00
2020.199C015.25103

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

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

E. IMPORTANT: Contractor is not is required to sign this document and return 1 copies to the issuing office.

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

Tax ID Number: 86-6052376

DUNS Number: 194910121

The purpose of this modification is to add CLIN 19 to provide funds for the Contractor to collect and deliver (b)(4) of convalescent plasma for the randomized clinical trial in hospitalized patients sponsored by the National Center for Advancing Translational Sciences, NIH.

ALL OTHER TERMS AND CONDITIONS REMAIN UNCHANGED.

Appr. Yr.: 2020 CAN: 199C015 Object Class: 25103

Period of Performance: 04/17/2020 to 04/16/2021

Continued ...

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

15A. NAME AND TITLE OF SIGNER (Type or print) Katherine Fry	16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) JEFFREY R. SCHMIDT
15B. CONTRACTOR/OFFEROR Katherine Fry (b)(6)	16B. UNITED STATES OF AMERICA Jeffrey R. Schmidt -S
15C. DATE SIGNED	16C. DATE SIGNED Digitally signed by Jeffrey R. Schmidt Date: 2020.08.10 16:05:27 -04'00'

Previous edition unusable

STANDARD FORM 30 (REV. 11/2016)
Prescribed by GSA FAR (48 CFR) 53.243

CONTINUATION SHEET

REFERENCE NO. OF DOCUMENT BEING CONTINUED
75A50120C00094/P00008

PAGE OF
2 2

NAME OF OFFEROR OR CONTRACTOR
AMERICA'S BLOOD CENTERS 1559070

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
19	Add Item 19 as follows: Collect and deliver (b)(4) of convalescent plasma for the randomized clinical trial in hospitalized patients sponsored by the National Center for Advancing Translational Sciences, NIH. Obligated Amount: \$425,000.00				425,000.00

MEMORANDUM

To: File
From: Jeffrey Schmidt, Contracting Officer
Date: August 12, 2020
Subject: Letter Contract No. 75A50120C00094
America's Blood Centers

The purpose of this memo is to document the source selection and steps taken to issue the subject letter contract.

The purpose of the contract is to allow the Government to acquire convalescent plasma units and the support and coordination services required to deliver those units.

The Government obligated \$750,000 for this contract with the understanding additional funds would be required at the time of contract definization.

The class J&A issued by the HHS Senior Procurement Executive was used. As a result, the POP is restricted to one year (without a determination from the Head of the Agency).

Timeline:

April 16, 2020	The program office introduced the Contracting Officer and the Contractor via email.
April 17, 2020	Contracting Officer provides proposed text and requirements of the Letter Contract to the Contractor Program office, Contracting Officer, and Contractor meet throughout the day to discuss an urgent need for the collection and distribution of convalescent plasma. Contracting Officer learns the Contractor does not have an active System for Award Management registration. Contracting Officer leverages FAR 18 flexibilities to award a contract to a contractor without an active sam.gov registration. The Contractor provides the needed banking information. Contracting Officer sends letter contract for signature; Contractor provides countersigned letter contract.

MEMORANDUM

To: File

From: Jeffrey Schmidt, Contracting Officer

Date: August 12, 2020

Subject: Modification 1 – Definitization
Contract No. 75A50120C00094
America's Blood Centers

The purpose of this modification is to definitize Letter Contract No. 75A50120C00094 entered into with the America's Blood Centers on April 17, 2020. This modification fully funds the base performance of the contract.

The Government began definitizing the letter contract by issuing a solicitation in the form of a Combined Synopsis Solicitation—this was done in accordance with the procedures of FAR Part 12 and 18. The solicitation was issued on April 24, 2020. The CSS included, among other things, the terms and conditions to be included in the subject contract, a description of the Government's method for evaluating the proposal, proposal instructions, and a requirement for the Contractor to provide a Statement of Work based on the objectives included in the CSS.

The Contractor submitted their proposal on April 29, 2020. That proposal included a Statement of Work, cost breakdowns for startup costs (at the Contractor's facility and at the Contractor's subcontractors' sites), and a per unit price for CCP. The per unit price for CCP was considered fair and reasonable. The Government requested additional information on the startup costs included in the proposal. The Contractor provided additional information including a breakdown of sites that would be receiving funding under the startup costs. The Government determined these prices to be fair and reasonable.

The Government negotiated Firm Fixed Price contract lines for all lines, including the startup costs (originally planned as Time and Materials contract lines) and for units.

The Government included a series of repeatable options to allow for collection of units beyond what was originally envisioned with the letter contract and included in the solicitation.

The Government and Contractor negotiated on the inclusion of several clauses outlined in FAR Clause 52.212-5. Including requirements around equal employment opportunity and subcontracting flow downs. A memo was issued by the Secretary of the Department of Labor that allowed for the waiver of typically EEO requirements—those waivers were incorporated into the subject contract.

The period of performance of the contract remains unchanged: 4/17/2020 – 4/16/2021.

This modification is in the best interest of the Government.

MEMORANDUM

To: File
From: Jeffrey Schmidt, Contracting Officer
Date: August 12, 2020
Subject: Modification 2 – Exercise Option 1 (CLIN 6)
Contract No. 75A50120C00094
America's Blood Centers

The purpose of the subject modification was to exercise Option 1 (CLIN6).

Option 1 (CLIN 6) is for the collection and delivery of (b)(4) of convalescent plasma to hospitals and medical centers participating in the Expanding Access Protocol Administered by the Mayo Clinic.

The Option is priced at \$8,415,000 and was fully funded using monies available for obligation at the time of obligation.

The period of performance of the contract remains unchanged: 4/17/2020 – 4/16/2021.

This is a unilateral modification; as such, a bilaterally signed copy was not requested from the Contractor.

This modification is in the best interest of the Government.

MEMORANDUM

To: File
From: Jeffrey Schmidt, Contracting Officer
Date: August 12, 2020
Subject: Modification 3 – Price Decease, Exercise Options, Increase Repeatability
Contract No. 75A50120C00094
America’s Blood Centers

The purpose of this modification is to (1) decrease the (b)(4) price (b)(4) of convalescent plasma in Options 2, 3, and 4 from (b)(4) (2) exercise Option 3 (b)(4) (3) exercise Option 4 (b)(4) and (4) increase the repeatability of Option 2 - CLIN 7 (b)(4)

- (1) Decrease the (b)(4) price of (b)(4) of convalescent plasma in Options 2, 3, and 4 (b)(4) (b)(4)

As the Contractor ramped up collection services, and the Government’s needs increased, it became apparent (b)(4)

(b)(4)

(b)(4) the Government requested the Contractor provide a breakdown of the (b)(4) price.

In an email dated June 3, the Contractor provided a breakdown of (b)(4) price. The new (b)(4) price is (b)(4)

To determine price reasonableness, the Government compared this pricing to the pricing for similar products, and the pricing under similar contracts.

- (2) Exercise Option 3 (b)(4) for (b)(4) and exercise Option 4 (b)(4) (b)(4)

As a result of this modification, the Contractor shall collect and deliver (b)(4) convalescent plasma to hospitals and medical centers participating in the Expanded Access Protocol administered by the Mayo Clinic (see CLIN 14) at a firm fixed price of (b)(4)

The Contractor is to collect and deliver these doses at the revised rate.

As a result of exercising Option 3 (b)(4) the repeatability of Option 3 - CLIN 8 is changed (b)(4)

As a result of exercising Option 4 (b)(4) the repeatability of Option 4 - CLIN 9 is changed (b)(4)

(3) Increase the repeatability of Option 2 - CLIN 7 (b)(4)

(b)(4)

The Government is anticipating the need for Covid Convalescent Plasma will increase in the near future. As a result, the Government and Contractor agree to include options to increase the total possible amount collected under contract by (b)(4)

As a result of increasing the repeatability of Option 2 (b)(4)
repeatability of Option 2 - CLIN 7 is (b)(4)

The Government relied on the class J&A to justify this change in scope.

The period of performance of the contract remains unchanged: 4/17/2020 – 4/16/2021.

This modification is in the best interest of the Government.

MEMORANDUM

To: File
From: Jeffrey Schmidt, Contracting Officer
Date: August 12, 2020
Subject: Modification 4 – Exercise Options, Adjust Collection Language
Contract No. 75A50120C00094
America’s Blood Centers

The purpose of this bilateral modification is to (1) adjust the descriptions in CLINs 7, 8, and 9 to provide for needed flexibility; (2) exercise Option 2 (b)(4); (3) exercise Option (b)(4); and (4) exercise (b)(4)

As a result of this modification, the Contractor shall collect and distribute up to (b)(4) of convalescent plasma for use in the Expanded Access Protocol, HIG manufacturing, stockpiling, and other uses as directed by BARDA (see CLIN 15) at a firm fixed price of (b)(4)

As a result of exercising Option 2 (b)(4) the repeatability of Option 2 - CLIN 7 is changed from (b)(4)

As a result of exercising Option 3 (b)(4) the repeatability of Option 3 - CLIN 8 is changed from (b)(4)

As a result of exercising Option 4 (b)(4) the repeatability of Option 4 - CLIN 9 is changed from (b)(4)

The “needed flexibility” is the result of the Government anticipating that CCP may be needed for uses beyond the Mayo Clinic EAP. To include, but not limited to: HIG manufacturing and stockpiling.

The period of performance of the contract remains unchanged: 4/17/2020 – 4/16/2021.

This modification is in the best interest of the Government.

MEMORANDUM

To: File
From: Jeffrey Schmidt, Contracting Officer
Date: August 12, 2020
Subject: Modification 5 – Exercise Options, Adjust Collection Language
Contract No. 75A50120C00094
America’s Blood Centers

The purpose of this modification is to: (1) correct the effective date of Modification P00003 to April 10, 2020; and (2) incorporate "Attachment 8 - Requirements for C3PO Doses" (2 pages) into the contract.

- (1) Correct the effective date of Modification P00003 to April 10, 2020.

The original effective date modification 3 was June 9, 2020.

Subsequent to executing modification 3, the Government learned doses of CCP were collected prior to June 9. Some doses were collected as early as April 10 without a way to reimburse the contractor; the Contractor had already delivered those doses to participants of the Mayo EAP.

By revising the effective date of modification 3, the Government is able to reimburse the Contractor for units delivered. This is in the best interest of the Government: (1) it is a show of good faith with the blood industry partner in this difficult time; and (2) ensures the Government is getting a many units as possible.

- (2) Incorporate "Attachment 8 – Requirements for C3PO Doses" (2 pages) into the contract.

The Government was asked to of enter into Material Transfer Agreement. The materials being transferred were being provided by (b)(4) and the administrators of the C3PO study (NHLBI, NIH).

Because the Government does not have a direct contract with (b)(4) the Government suggested to the Contractor we modify the contract to include the language (b)(4)

(b)(4)

(b)(4) NHLBI was in agreement with its inclusion.

The period of performance of the contract remains unchanged: 4/17/2020 – 4/16/2021.

This modification is in the best interest of the Government.

MEMORANDUM

To: File
From: Jeffrey Schmidt, Contracting Officer
Date: August 12, 2020
Subject: Modification 6 – EUA Language, Surge Activities
Contract No. 75A50120C00094
America’s Blood Centers

The purpose of this modification is to: (1) modify CLIN 15 to provide language to account for the possibility of an Emergency Use Authorization being granted for convalescent plasma; (2) add CLIN 16 to account for the surge activities that required to expedite the collection of (b)(4) and (3) add CLIN 17 to account for the advance purchase of collection kits/bags.

- (1) Modify CLIN 15 to provide language to account for the possibility of an Emergency Use Authorization being granted for convalescent plasma.

The Government is preparing for the possibility that an Emergency Use Authorization would be issued for CCP. Any EUA for CCP would include a titering threshold. If doses do not meet that threshold, the Contractor will not be reimbursed for that dose.

Modification 6 included the following language: If, under the performance of this option, an Emergency Use Authorization is granted for the use of convalescent plasma and there is a titer requirement threshold for use as convalescent plasma, it is agreed that some (b)(4) may not meet the titer threshold. ABC will invoice (b)(4) for every (b)(4) that does not meet the titer threshold instead of the (b)(4). The (b)(4) prices under this contract line do not include surge pricing or cost for the purchase of collection kits/bags. Those prices are provided for under Contract Line Item Numbers 16 and 17. The Government and the Contractor agree that the price (b)(4) that does not meet the titer threshold may be renegotiated during contract performance. The Government and the Contractor agree to conduct any renegotiations in good faith.

The Contractor provided (b)(4). The Government confirmed (b)(4).

- (2) Add CLIN 16 to account for the surge activities that required to expedite the collection of units.

It became apparent to the Government that there are several limiting factors in the collection of units, including: procurement of collection supplies, APH equipment, donor incentives, and PPE.

The Contractor has proposed (b)(4) which would result in faster collection rates.

The Government has analyzed (b)(4) submitted by the Contractor and determined them to be reasonable.

- (3) Add CLIN 17 to account for the advance purchase of collection kits/bags.

Related to the other surge pricing, the Government is including a contract line for the purchase of (b)(4) This is necessary to give the bag manufacturers adequate assurances that they will be compensated for ramping up their production. Without this assurance the limiting factor in CCP collection could be collection bag/kits scarcity.

The period of performance of the contract remains unchanged: 4/17/2020 – 4/16/2021.

This modification is in the best interest of the Government.

MEMORANDUM

To: File

From: Jeffrey Schmidt, Contracting Officer

Date: August 12, 2020

Subject: Modification 7 – Surge Rate
Contract No. 75A50120C00094
America's Blood Centers

The purpose of this modification is to add CLIN 18 to account for surge activities that require expedited collection of convalescent plasma units.

The Government is now requesting the Contractor ramp up to be able to collect (b)(4) per week. To do so, the Contractor proposed an increase to the (b)(4) price that would account for the additional ramp up/surge activities, to include increase in staffing and donor incentives.

The Government reviewed the additional costs and determined them to be fair and reasonable for the anticipated increase in collection.

The period of performance of the contract remains unchanged: 4/17/2020 – 4/16/2021.

This modification is in the best interest of the Government.

MEMORANDUM

To: File

From: Jeffrey Schmidt, Contracting Officer

Date: August 12, 2020

Subject: Modification 8 – NCATS Clinical Trial
Contract No. 75A50120C00094
America's Blood Centers

The purpose of this modification is to add CLIN 19 to provide funds for the Contractor to collect and deliver (b)(4) of convalescent plasma for the randomized clinical trial in hospitalized patients sponsored by the National Center for Advancing Translational Sciences, NIH.

The Government relied on the Unusual and Compelling Class J&A (issued by the HHS SPE and included in the contract file) to justify expanding the scope of the contract to include this requirement. The Contractor has the infrastructure to deliver the units under CLIN 19 in an expedited timeline.

The period of performance of the contract remains unchanged: 4/17/2020 – 4/16/2021.

This modification is in the best interest of the Government.