

AGREEMENT BETWEEN

UNITED STATES ARMY CONTRACTING COMMAND
Aberdeen Proving Grounds (APG) - Natick Division

AND

America's Blood Centers
1300 Division Rd, Suite 102
West Warwick, RI
02893-7558

Agreement No.: W911QY-21-9-0006

Effective Date: 30 October 2020

Total Amount of the Agreement: (b) (4)

Total Government Funding for the Agreement: (b) (4)

Authority:

10 U.S.C. § 2371b, Section 815 of the 2016 National Defense Authorization Act, P.L. 114-92, as amended.

IN WITNESS WHEREOF, each Party has executed this Agreement by signature of its authorized representative.

SIGNATURES:

Awardee

(b) (6) (b) (6) (b) (6)
Date: 2020.10.30 17:43:22 -0400

Signature

(b) (6)

Printed Name

Chief Executive Officer

Title

10/30/2020

Date

Government

(b) (6) (b) (6)

Signature

(b) (6)

Printed Name

Agreements Officer

Title

30 October 2020

Date

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- A – Statement of Objectives – dated 16 October 2020
- B – Project Plan – dated 28 October 2020

ARTICLE I: SCOPE OF THE AGREEMENT

A. Background

This Other Transaction Agreement (OTA) is awarded America's Blood Centers, hereinafter referred to as "ABC". The principle purpose of this OTA is to develop a novel prototype process to expand the capabilities for the collection of COVID-19 Convalescent Plasma (CCP). The process shall include an innovative approach to increase donor activity, expand physical capacity, and contribute to a national reserve for CCP in accordance with the Statement of Objectives and the Project Plan.

B. Definitions

"Agreement" or "OTA" or "Project Agreement" refers to the Other Transaction Agreement, as authorized under 10 U.S.C. 2371b, between the Government and America's Blood Centers, Agreement No. W911QY-21-9-0006.

"Agreements Officer (AO)" is the United States Army Contracting Command – APG – Natick Division warranted Contracting Officer authorized to sign the final agreement for the Government.

"Agreements Officer's Representative (AOR)" is the individual designated by the Government on a per project basis to monitor all technical aspects; the AOR shall only assist in agreement administration of the specific project to the extent expressly delegated such administration authority in writing in the Project Agreement by the responsible Agreements Officer.

"Contracting Activity" means an element of an agency designated by the agency head and delegated broad authority regarding acquisition functions. It also means elements or another agency designated by the director of a defense agency, which has been delegated contracting authority through its agency charter.

"Date of Completion" is the date on which all work is completed or the date on which the period of performance ends.

"Development" means the systematic use, under whatever name, of scientific and technical knowledge in the design, development, test, or evaluation of an existing or potential new technology, product or service (or of an improvement in an existing technology, product or service) for the purpose of meeting specific performance requirements or objectives. Development includes the research functions of design engineering, prototyping, and engineering testing.

"Effective Date" means the date when this Agreement is signed and executed by the Agreements Officer for the Government.

"Expenditure-Based OTA" means agreements where payments are exclusively or primarily based on amounts generated from the awardee's financial or cost records.

"Government" means the U.S. Government.

"Government Fiscal Year" means the period commencing on October 1 and ending September 30 of the following calendar year.

“Other Transactions Agreement (OTA)” is the term commonly used to refer to the 10 USC 2371b authority to enter into transactions other than contracts, grants or cooperative agreements. The Department of Defense (DoD) currently has authority to make awards that are directly relevant to enhancing the mission effectiveness of military personnel and the supporting platforms, systems, components, or materials proposed to be acquired or developed by the Department of Defense, or to improvement of platforms, systems, components, or materials in use by the armed forces. OTAs are acquisition instruments that generally, are not subject to the federal laws and regulations governing procurement (FAR based) contracts. As such, they are not required to comply with the Federal Acquisition Regulation (FAR), its supplements (i.e. DFARS) or laws that are limited in applicability to procurement contracts.

“Parties” means Government and ABC by its authorized agent where collectively identified and “Party” where each entity is individually identified.

“Project” means the overall effort to be funded by the Agreement, which is described in the Statement of Objectives & Awardee’s Project Plan appended to this Agreement as Attachments A and B.

“Signatory Authority” refers to the individual that has the authority to legally bind a party to an agreement.

“Successful Completion” means the efforts conducted under the Agreement: (1) met any key technical goals of the project; (2) satisfied any success metrics incorporated into the Agreement; or (3) accomplished a particularly favorable or unexpected result that justifies the transition to production. The prototype will be successful under the Agreement if capabilities have been proven to stimulate the collection of 15,000 units of CCP per week, for a sustained period of 12 weeks, or a national reserve goal of 100,000 units is achieved. For the avoidance of doubt, ABC’s right to reimbursement is not contingent on “Successful Completion” of the Project, but rather reasonable expenditures in pursuit of the Project.

C. Scope

1. This Other Transaction Authority for Prototypes Agreement (the “Agreement”) is entered into between the Government and the Awardee on the Effective Date set forth above. For the avoidance of doubt, this Agreement is entered into pursuant to 10 U.S.C. § 2371b and is not a procurement contract governed by the Federal Acquisition Regulation (“FAR”), a grant, or cooperative agreement. The FAR and the Defense Federal Acquisition Regulation Supplement (DFARS) apply only as specifically referenced herein. This Agreement is not intended to be, nor will it be construed as, forming, by implication or otherwise, a partnership, a corporation, or other business organization. This Agreement is not subject to the Bayh-Dole Act, 35 U.S.C. §§ 200-212.

2. The Parties agree that the ultimate purpose of this Agreement is for the development of a novel process to expand the capabilities for the collection of COVID-19 Convalescent Plasma (CCP), herein referred to as the “Prototype”. In consideration for Government funding under this Agreement, the Awardee will provide research and development directed towards the Prototype, as described in the Statement of Objectives and the Awardee’s Project Plan (PP), which are incorporated herein and attached hereto as Attachments A and B.

ARTICLE II: TERM AND TERMINATION

A. The Term of this Agreement

The period of performance for this OTA shall be for twelve (12) months from the date the OTA is executed. Provisions of this Agreement, which, by their express terms or by necessary implication, apply for periods of time other than specified in Article II herein, shall be given effect, notwithstanding this Article.

B. Early Termination of Agreement Provision

1. Subject to a reasonable determination that the project, or an activity funded under the project, will not produce beneficial results commensurate with the expenditure of resources, the Government may terminate performance of work under this OTA, in whole or in part, if the AO determines that a termination is in the Government's interest and after at least thirty (30) calendar days' prior written notice to the Awardee. The AO shall terminate by delivering to ABC a Notice of Termination specifying the extent of termination and the effective date. Should the Government exercise this right, ABC has thirty (30) days from the termination effective date to submit a settlement proposal to which the parties will negotiate a good faith agreement upon. The parties shall use best efforts to reach an agreed upon settlement within ninety (90) days of proposal submission.

After receipt of a Notice of Termination, and except as directed by the AO, ABC shall without undue delay proceed with the following obligations, regardless of any delay in determining or adjusting any amounts due:

- a. Stop work and direct its subcontractors/vendors/suppliers/partners to stop work as specified in the notice.
- b. Place no further orders for materials, services, or facilities, except as necessary to complete the continued portion of the OTA.
- c. Terminate all orders to the extent they relate to the work terminated, and such termination is possible.
 - i. Assign to the Government, as directed by the AO, all right, title, and interest of ABC arising under the orders terminated, in which case the Government shall have the right to settle or to pay any termination settlement proposal arising out of those terminations.
 - ii. With approval or ratification to the extent required by the AO, settle all outstanding liabilities and termination settlement proposals arising from the termination of orders; the approval or ratification will be final for purposes of this clause.
 - iii. As directed by the AO, deliver to the Government the completed or partially completed plans and other information that, if the project had been completed, would have been required to be delivered to the Government.

- iv. Complete performance of any work not terminated, if applicable.

In the event of a termination of this Agreement, the Government shall have patent rights as described in Article XII, Intellectual Property Rights, and rights in Data as described in Article XI, Data Rights. Failure of the Parties to agree to an equitable adjustment shall be resolved pursuant to Article IX, Disputes.

Nothing in this section shall be construed as a limitation of the rights of either party in the event of a breach of contract or default by the other party.

C. Stop Work Clause

As directed by the AO, ABC shall stop all, or any part, of the work called for under this Agreement for a period of 90 days after the written order is delivered, and for any further period to which the parties may agree. The order shall be specifically identified as a stop-work order issued under this Article. Upon receipt of the order, ABC shall immediately comply with its terms and take all reasonable steps to minimize the incurrence of costs allocable to the work covered by the order during the period of work stoppage. Within a period of 90 days after a stop-work is delivered, or within any extension of that period to which the parties shall have agreed, the AO shall either:

1. Cancel the stop-work order; or
2. Terminate the work covered this Agreement.

If a stop work order issued under this clause is canceled, ABC shall resume work. The Government shall make an equitable adjustment in the delivery schedule or negotiated price, or both, and the Government's share of this Agreement shall be modified, in writing, accordingly, if—

- i. The stop-work order results in an increase in the time required for, or in the cost properly allocable to, the performance of any part of this Agreement; and
- ii. ABC asserts its right to the adjustment within 30 days after the end of the period of work stoppage; however, if the Government decides the facts justify the action, the Government may receive and act upon a proposal submitted at any time before final payment under this Agreement.

ARTICLE III. PROJECT MANAGEMENT

A. Project Governance

The Awardee is responsible for the overall management of the project development and related project decisions. The Government will have continuous involvement with the Awardee. The Awardee shall provide access to project progress and results in accordance with the Awardee's Project Plan located in Attachment B.

B. Key Personnel

The Awardee shall designate a Project Lead and Project Sub-Lead responsible for facilitating the communications, reporting, and meetings between the Parties. Project Lead/Project Sub-Lead point of

contact information below:

Project Lead: (b) (6)
Senior Director, Federal Government Affairs
America's Blood Centers
(b) (6)

Project Sub-Lead: (b) (6) President & CEO
Blood Centers of America
(b) (6)

The key personnel of Awardee, as listed in Attachment B, are considered to be critical to the successful performance of this Agreement. Prior to replacing these key personnel, the Awardee shall provide written notification to the AO. The Awardee shall demonstrate that the qualifications of the proposed substitute personnel are generally equivalent to or better than the qualifications of the personnel being replaced.

ARTICLE IV: AGREEMENT ADMINISTRATION

In no event shall any understanding or agreement, modification, change order, or other matter in deviation from the terms of this Agreement between the Awardee and a person other than the AO be effective or binding upon the Government. All such actions must be formalized by a proper contractual document executed by the AO.

Government Oversight Team Representatives:

AO: (b) (6)
Agreements Officer
ACC-APG-Natick
(b) (6)

AS: (b) (6)
Agreements Specialist
ACC-APG-Natick
(b) (6)

AOR: (b) (6)
Agreements Officer Representative
Lead, Supply Chain Convalescent Plasma / HiG
Operation Warp Speed (b) (6)

Awardee Representatives:

Project Sponsor: (b) (6)
Chief Executive Officer
America's Blood Centers
(b) (6)

ARTICLE V: PERFORMANCE OBJECTIVES AND CHANGES

- A. The Statement of Objectives (SOO), Attachment A, describes the objectives which emphasize the activities that will be undertaken by the Awardee to achieve the project goals. These activities are outlined in the Project Plan, Attachment B.
- B. Recommendations for modifications, including justifications to support any changes to the SOO, will be documented in a letter and submitted by Awardee to the AO. This letter will detail the technical, chronological and financial impact, if any, of the proposed modification to the project. Any resultant modification is subject to the mutual agreement of the Parties. The Government is not obligated to pay for additional or revised costs unless and until this Agreement is formally revised by the AO and made part of this Agreement. Any modification to this Agreement to account for recommended changes in the SOO will be considered a supplemental agreement.
- C. Review of Recommendations: The AO will be responsible for the review and verification of any recommendations to revise or otherwise modify the Agreement, the SOO, payment terms, or other proposed changes to the terms and conditions of this Agreement.
- D. Minor Modifications: The Government may make minor or administrative Agreement modifications unilaterally (e.g., changes in the paying office or appropriation data, changes to Awardee personnel proposed by Awardee, etc.).
- E. Amending the Agreement: The Government will be responsible for effecting all modifications to this Agreement, with the concurrence of the Awardee for modifications that are not minor or administrative. Administrative and material matters under this Agreement will be referred to AO.
- F. Modification Communications: No other communications, whether oral or in writing, that purport to change this Agreement are valid.
- G. Government Property: Not Applicable

ARTICLE VI: MEETINGS AND TECHNICAL DATA REQUIREMENTS

A. Meetings

Monthly Status Meetings: The Awardee's Project Lead, and Project Sub-Lead shall convene monthly with the Government Oversight Team to discuss the status of the project and review the submitted monthly report. This meeting shall coincide with the submission of the monthly reports, and should occur mid-month accordingly.

The Government Oversight Team and Awardee Project Lead and Sub-Lead may agree to ad hoc meetings to address specific issues or to convey time-sensitive updates related to the project.

B. Technical Data

1. Monthly Progress & Expenditure Report: No later than the 10th (tenth) day of each month during the Period of Performance, a monthly report shall be furnished electronically to the Government Oversight Team which encompasses the previous month's notable progress, issues encountered, project risks identified and mitigation taken to reduce them, monthly expenditures & total project expenditures to date.
2. Project Report: No later than 90 days after completion of the project, the Awardee shall electronically furnish a final project report that provides an overview of the successes and failures experienced in the development of the prototype to enable the USG to prepare for future pandemic blood collection surge missions.
3. Prototype Operation Plan: No later than 90 days after completion of the project and determination of the prototype's success by the Government, a detailed and replicable Operation Plan shall be furnished electronically to the Government Oversight Team. This Operation Plan shall illustrate the successful technical approach and processes undertaken to increase donor activity, expand physical capacity, and contribute to the national reserve for CCP, in accordance with the project goals in the Statement of Objectives.
4. Deliverables as outlined in the Awardee's Project Plan, to be electronically furnished to the Government Oversight Team, to include:
 - a. Weekly collection and distribution files with all supporting documentation
 - b. Weekly inventory reports by ABO type for units stockpiled

ARTICLE VII: INSPECTION/ACCEPTANCE

- A. Inspection: The Government has the right to inspect and test all work called for by this Agreement, to the extent practicable at all places and times, including the period of performance, and in any event before acceptance. The Government may also inspect the premises of the Awardee engaged in Agreement performance. The Government shall perform inspections and tests in a manner that will not unduly delay the work.
- B. The Government shall accept or reject the work as promptly as practicable after completion/delivery, unless otherwise specified in the Agreement. Government failure to inspect and accept or reject the work shall not relieve the Awardee from responsibility, nor impose liability on the Government, for nonconforming work. Work is nonconforming when it is defective in material or workmanship or is otherwise not in conformity with Agreement requirements. The Government has the right to reject nonconforming work. The Government's inspection and acceptance of Project work performed by ABC will not exceed 90 days after completion or delivery by ABC.

ARTICLE VIII: FINANCIAL MATTERS

- A. Obligation: Except as specified in Article IX: Disputes, the Government's liability to make payments to the America's Blood Centers is limited only to those funds obligated under this Agreement or by modification to the Agreement. ACC-APG-Natick may incrementally fund this Agreement. If modification becomes necessary in performance of this Agreement, pursuant to Article V of this Agreement, the AO

and America's Blood Centers shall establish and execute mutually agreed to revised payment terms consistent with the current Project Plan.

B. Payments. The total amount of this Agreement shall be obligated at the time of award. This Agreement is an expenditure type OTA. The charges may be reported on a cash or accrual basis, as long as the methodology is disclosed and is consistently applied. The amounts of interim payments or the total amount ultimately paid to ABC is based on the amounts ABC expends on Project costs plus an agreed administration fee. If ABC completes the Project specified at the time of award before it expends all of the agreed-upon Federal funding, the Federal Government may recover the unexpended balance of funds.

Payments shall be made on a monthly basis for the reimbursement of allowable costs within the scope of the Project, & in accordance with the Project Plan, incurred during the period of performance up to the agreed upon project budget. Proper documentation shall be submitted to justify all costs submitted for expenditure reimbursement. Proper documentation includes, but is not limited to: supporting quotes, invoices paid, industry compensation records, and proof of actual expenses incurred. Payments shall be made within 30 days of the submission of a proper invoice as set forth in Section VIII.F.

C. Accounting System Requirements: Prior to the submission of invoices, ABC shall have and maintain an established accounting system which complies with Generally Accepted Accounting Principles (GAAP). Consistent with this stipulation, an acceptable accounting system will be one in which all cash receipts and disbursements are controlled and documented properly.

D. Use of Funds. Federal funds are to be used only for costs that a reasonable and prudent person would incur in carrying out the Project.

E. Allowable Costs. The allowability of costs will be determined by the Agreements Officer in good faith-consultation with ABC, with reference to the OMB Uniform Guidance at 2 CFR part 200, subpart E and appendix IV in effect on the date of the agreement.

F. Invoicing: ABC shall submit invoices for processing, according to the payment terms above, to the AOR for payment approval via The Invoice, Receipt, Acceptance, and Property Transfer (iRAPT) application of the Wide Area Work Flow (WAWF) system, according to the guidelines set forth in DFARS Subpart 232.70 and DFARS 252.232-7003 Electronic Submission of Payment Requests and Receiving Reports. Payments will be made by the Defense Finance and Accounting Service (DFAS) Indianapolis – GFEBS, HQ0490, 8899 E 56th Street, Indianapolis, IN 46249-3800.

WAWF Provision:

1. Definitions. As used in this clause--

Department of Defense Activity Address Code (DoDAAC) is a six-position code that uniquely identifies a unit, activity, or organization.

Document type means the type of payment request or receiving report available for creation in Wide Area WorkFlow (WAWF).

Local processing office (LPO) is the office responsible for payment certification when payment certification is done external to the entitlement system.

2. Electronic invoicing. The WAWF system is the method to electronically process vendor payment requests and receiving reports, as authorized by DFARS 252.232-7003, Electronic Submission of Payment Requests and Receiving Reports.
3. WAWF access. To access WAWF, the Recipient shall (i) have a designated electronic business point of contact in the System for Award Management at <https://www.acquisition.gov>; and (ii) be registered to use WAWF at <https://wawf.eb.mil/> following the step-by-step procedures for self-registration available at this website.
4. WAWF training. The Recipient should follow the training instructions of the WAWF Web-Based Training Course and use the Practice Training Site before submitting payment requests through WAWF. Both can be accessed by selecting the "Web Based Training" link on the WAWF home page at <https://wawf.eb.mil/>.
5. WAWF methods of document submission. Document submissions may be via Web entry, Electronic Data Interchange, or File Transfer Protocol.
6. WAWF payment instructions. The Recipient must use the following information when submitting payment requests and receiving reports in WAWF for this contract/order:
 - a. Document type. The Recipient shall use the following document type: Invoice and Receiving Report (Combo)
 - b. Inspection/acceptance location. The Recipient shall select the following inspection/acceptance location(s) in WAWF, as specified by the contracting officer.
 - c. Document routing. The Recipient shall use the information in the Routing Data Table below only to fill in applicable fields in WAWF when creating payment requests and receiving reports in the system.

Routing Data Table*

Field Name in WAWF	Data to be entered in WAWF
Pay Official DoDAAC	HQ0490
Issue By DoDAAC	W911QY
Admin DoDAAC	W911QY
Inspect and Accept By DoDAAC	W56XNH
Ship To Code	W56XNH

Payee Information: As identified at the System for Award Management.

America's Blood Centers
 Cage Code: 3C8G9
 DUNS: 194910121

i. Payment request and supporting documentation. The Recipient shall ensure a payment request includes appropriate contract line item and subline item descriptions of the work performed or supplies delivered, unit price/cost per unit, fee (if applicable), and all relevant back-up documentation in support of each payment request.

ii. WAWF email notifications. The Recipient shall enter the email address identified below in the "Send Additional Email Notifications" field of WAWF once a document is submitted in the system.

7. WAWF point of contact.

1. The Recipient may obtain clarification regarding invoicing in WAWF from the following contracting activity's WAWF point of contact.

AOR: (b) (6)

2. For technical WAWF help, contact the WAWF helpdesk at 866-618-5988.

G. Electronic Fund Transfer: ABC must be enrolled in EFT by contacting the paying office designated in the Agreement and requesting form SF 3881, Automated Clearing House (ACH) Vendor/Miscellaneous Payment Enrollment Plan. This form must be completed by ABC and ABC's financial institution, and returned to the paying office. The paying office will complete the process and notify ABC that EFT enrollment is complete. All payments under this agreement will be held until ABC provides the required EFT enrollment information. Registration in the System Award for Management (SAM) is mandatory.

H. Financial Records and Reports: Should cost sharing procedures be implemented for funding a particular Project, ABC shall maintain adequate records to account for Federal funds received under this Agreement and shall maintain adequate records to account for ABC's Project Agreement funding provided under this Agreement.

I. Comptroller General Access to Records: To the extent that the total Government payments under this Agreement exceed \$5,000,000, the Comptroller General, at its discretion, shall have access to and the right to examine records of any Party to the Agreement or any entity that participates in the performance of this Agreement that directly pertain to, and involve transactions relating to, the Agreement for a period of three (3) years after final payment is made. This requirement shall not apply with respect to any Party to this Agreement or any entity that participates in the performance of the Agreement, or any subordinate element of such Party or entity, that has not entered into any other agreement (contract, grant, cooperative agreement, or "other transaction") that provides for audit access by a government entity in the year prior to the date of this Agreement. This paragraph only applies to any record that is created or maintained in the ordinary course of business or pursuant to a mandatory and applicable provision of law. The terms of this paragraph shall be included in all sub-agreements to the Agreement other than sub-agreements with a component of the U.S. Government. The Comptroller General may not examine records pursuant to a clause included in an agreement more than three years after the final payment is made by the United States under the agreement.

ARTICLE IX: DISPUTES

A. General

The Parties shall communicate with one another in good faith and in a timely and cooperative manner when raising issues under this Article.

B. Dispute Resolution Procedures

Any disagreement, claim or dispute between ACC-APG-Natick Division and America's Blood Centers concerning questions of fact or law arising from or in connection with this Agreement, and, whether or not involving an alleged breach of this Agreement, may be raised only under this Article.

Whenever disputes, disagreements, or misunderstandings arise, the Parties shall attempt to resolve the issue(s) involved by discussion and mutual agreement as soon as practicable. In no event shall a dispute, disagreement or misunderstanding which arose more than three (3) months prior to the notification made under this article constitute the basis for relief under this article unless the Chief of the Contracting Office, ACC-APG-Natick Division in the interest of justice waives this requirement.

Failing resolution by mutual agreement, the aggrieved Party shall document the dispute, disagreement, or misunderstanding by notifying the other Party (through the respective AO or Project Sponsor, as the case may be) in writing documenting the relevant facts, identifying unresolved issues, specifying the clarification or remedy sought, and documenting the rationale as to why the clarification/remedy is appropriate. Within ten (10) working days after providing notice to the other Party, the aggrieved Party may, in writing, request a decision by the Chief of the Contracting Office, ACC-APG-Natick Division. The other Party shall submit a written position on the matter(s) in dispute within thirty (30) calendar days after being notified that a decision has been requested. The Chief of the Contracting Office, ACC-APG-Natick, will conduct a review of the matter(s) in dispute and render a decision in writing within thirty (30) calendar days of receipt of such position. Any such decision is final and binding, unless a Party shall, within thirty (30) calendar days request further review as provided by this article.

If requested within thirty (30) calendar days of the decision by the Chief of the Contracting Office, ACC-APG-Natick Division, further review will be conducted by the President of America's Blood Centers Board and the ACC-APG-Senior Contracting Official. In the event of a decision, or in absence of a decision within sixty (60) calendar days of referral to the President of America's Blood Centers and the ACC-APG-Senior Contracting Official (or such other period as agreed to by the parties), either party may pursue any right or remedy provided by law. Alternatively, the parties may agree to explore and establish an Alternate Disputes Resolution procedure to resolve this dispute.

C. Limitation of Liability and Damages

In no case shall the Government's financial liability exceed the amount obligated under this agreement.

In no event shall the liability of America's Blood Centers exceed the administrative fees received for their performance of this Agreement.

No Party shall be liable to any other Party for consequential, punitive, special and incidental damages or other indirect damages, whether arising in contract (including warranty), tort (whether or not arising from the negligence of a Party) or otherwise, except to the extent such damages are caused by a Party's

willful misconduct; Notwithstanding the foregoing, claims for contribution toward third-party injury, damage, or loss are not limited, waived, released, or disclaimed.

ARTICLE X: CONFIDENTIAL INFORMATION

A. Definitions

“Disclosing Party” means America’s Blood Centers, or their subcontractors or suppliers, or the Government who discloses Confidential Information as contemplated by the subsequent Paragraphs.

“Receiving Party” means America’s Blood Centers, or their subcontractors or suppliers, or the Government who receives Confidential Information disclosed by a Disclosing Party.

“Confidential Information” means information and materials of a Disclosing Party which are designated as confidential or as a Trade Secret in writing by such Disclosing Party, whether by letter or by use of an appropriate stamp or legend, prior to or at the same time any such information or materials are disclosed by such Disclosing Party to the Receiving Party. Notwithstanding the foregoing, materials and other information which are orally, visually, or electronically disclosed by a Disclosing Party, or are disclosed in writing without an appropriate letter, stamp, or legend, shall constitute Confidential Information or a Trade Secret if such Disclosing Party, within thirty (30) calendar days after such disclosure, delivers to the Receiving Party a written document or documents describing the material or information and indicating that it is confidential or a Trade Secret, provided that any disclosure of information by the Receiving Party prior to receipt of such notice shall not constitute a breach by the Receiving Party of its obligations under this Paragraph. “Confidential Information” includes any information and materials considered a Trade Secret by ABC on its own behalf or on behalf of their subcontractors or suppliers.

“Trade Secret” means all forms and types of financial, business, scientific, technical, economic, or engineering or otherwise proprietary information, including, but not limited to, patterns, plans, compilations, program devices, formulas, designs, prototypes, methods, techniques, processes, procedures, programs, or codes, whether tangible or intangible, and whether or how stored, compiled, or memorialized physically, electronically, graphically, photographically, or in writing if:

1. The owner thereof has taken reasonable measures to keep such information secret; and
2. The information derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable through proper means by, the public.

B. Exchange of Information: The Government may from time to time disclose Government Confidential Information to ABC and its subcontractors or suppliers, in connection with Annual Plan and similar processes or particular projects, and America’s Blood Centers their subcontractors or suppliers, may from time to time disclose information that is Trade Secret or Confidential Information to the Government in connection with the OTA, an OTA project proposal, Payment terms or Instruction, Project Agreement, or performance thereunder. Neither the Government nor America’s Blood Centers or their subcontractors or suppliers shall be obligated to transfer Confidential Information or Trade Secrets independently developed by the Government or America’s Blood Centers or their subcontractors or suppliers, absent an express written agreement between the Parties providing the terms and conditions

for such disclosure.

C. Confidentiality and Authorized Disclosure: The Receiving Party agrees, to the extent permitted by law, that Confidential Information and Trade Secrets shall remain the property of the Disclosing Party (no one shall disclose unless they have the right to do so), and that, unless otherwise agreed to by the Disclosing Party, Confidential Information and Trade Secrets shall not be disclosed, divulged, or otherwise communicated by it to third parties or used by it for any purposes other than in connection with specified project efforts and the licenses granted in Article X, Patent Rights, and Article XI, Data Rights, provided that the duty to protect such "Confidential Information" and "Trade Secrets" shall not extend to materials or information that:

- Are received or become available without restriction to the Receiving Party under a proper, separate agreement,
- Are not identified with a suitable notice or legend per Article entitled "Confidential Information" herein,
- Are lawfully in possession of the Receiving Party without such restriction to the Receiving Party at the time of disclosure thereof as demonstrated by prior written records,
- Are or later become part of the public domain through no fault of the Receiving Party,
- Are received by the Receiving Party from a third party having no obligation of confidentiality to the Disclosing Party that made the disclosure,
- Are developed independently by the Receiving Party without use of Confidential Information or Trade Secrets as evidenced by written records,
- Are required by law or regulation to be disclosed; provided, however, that the Receiving Party has provided written notice to the Disclosing Party promptly so as to enable such Disclosing Party to seek a protective order or otherwise prevent disclosure of such information.

D. Return of Proprietary Information: Upon the request of ABC, the Government shall promptly return all copies and other tangible manifestations of the Confidential Information or Trade Secrets disclosed.

Upon request by the Government, ABC shall promptly return all copies and other tangible manifestations of the Confidential Information disclosed by the Government. As used in this section, tangible manifestations include human readable media as well as magnetic and digital storage media.

E. Term: Except to the extent covered by and subject to other provisions of this Agreement or the specific Project Agreement, the obligations of the Receiving Party under this Article shall continue for a period of five (5) years after the expiration or termination of this Agreement.

The Government and ABC shall flow down the requirements of this Article VI to their respective personnel, agents, partners, and team members receiving such Confidential Information or Trade Secrets under this OTA.

ARTICLE XI: DATA RIGHTS

A. Definitions

1. "Commercial Computer Software" as used in the Article is defined in DFARS 252-227-7014(a) (1) (Jun 1995).
2. "Commercial Computer Software License" means the license terms under which Commercial Computer Software is sold or offered for sale, lease or license to the general public.
3. "Computer Data Base" as used in this Agreement, means a collection of data recorded in a form capable of being processed by a computer. The term does not include computer software.
4. "Computer program" as used in this Agreement means a set of instructions, rules, or routines in a form that is capable of causing a computer to perform a specific operation or series of operations.
5. "Computer software" as used in this Agreement means computer programs, source code, source code listings, object code listings, design details, algorithms, processes, flow charts, formulae and related material that would enable the software to be reproduced, recreated or recompiled. Computer software does not include computer data bases or computer software documentation.
6. "Computer software documentation" means owner's manuals, user's manuals, installation instructions, operating instructions, and other similar items, regardless of storage medium, that explain the capabilities of the computer software or provide instructions for using the software.
7. "Data" as used in this Article of this Agreement, means computer software, computer software documentation, form, fit and function data, and technical data as defined in this Article.
8. "Form, fit and function data" means technical data that describes the required overall physical, functional and performance characteristics (along with the qualification requirements, if applicable) of an item, component, or process to the extent necessary to permit identification of physically and functionally interchangeable items.
9. "Government purpose rights" means the rights to use, modify, duplicate or disclose the "Data" licensed with such rights under this Agreement within the Government for United States Government purposes only; and to release or disclose data outside the Government to any authorized persons pursuant to an executed non-disclosure agreement for such persons' use, modification, or reproduction for United States Government purposes only. United States Government purposes include Foreign Military Sales purposes and competitive re-procurement.
10. "Limited rights" as used in this Article is as defined in DFARS 252.227-7013(a) (14).
11. "Restricted rights" as used in this Article is as defined in DFARS 252.227-7014(a) (15).
12. "Specially Negotiated License Rights" are those rights to Data that have been specifically negotiated between the Government and ABC.
13. "Technical data" means recorded information, regardless of the form or method of the

recording, of a scientific or technical nature (including computer software documentation). The term does not include computer software or data incidental to contract administration, such as financial and/or management information.

14. "Unlimited rights" means the rights to use, modify, duplicate, release, or disclose Data, in whole or in part, in any manner, and for any purpose whatsoever, and to have or authorize others to do so.

B. Data Categories:

1. Category A is Data developed and paid for totally by non-governmental funds, whether pre-existing or concurrently developed proprietary data, trade secret data, or data related to America's Blood Center's services. America's Blood Centers retains all rights to Category A Data.
2. Category B is any Data developed and delivered under this Agreement, using Government funds, which cannot be disclosed without compromising the Category A data.
3. Category C is any America's Blood Centers developed Data, excluding Category A and B data, developed and delivered during the performance of work under this Agreement.
4. Category D is third party proprietary data used in performance of work under this Agreement, including but not limited to, technical data, software, trade secrets and mask works.

Any Data developed outside of this Agreement with Government funding in whole or in part under a Government agreement, contract or subcontract shall have the rights negotiated under such prior agreement, contract or subcontract; the Government shall get no additional rights in such Data under this Agreement.

C. Allocation of Principal Rights

1. No deliveries to the Government of Category A and B data are contemplated or required under this Agreement. The Government reserves the right to negotiate certain rights in Category A and B data with the owner of the data. The existence and use of Category A or B data will be disclosed in each project proposal.
2. The Government shall have immediate and irrevocable Government Purpose Rights to all Category C Data.
3. Data that will be delivered, furnished, or otherwise provided to the Government under this Agreement, in which the Government has previously obtained rights, shall be delivered, furnished, or provided with the pre-existing rights, unless (a) the parties have agreed otherwise, or (b) any restrictions on the Government's rights to use, modify, reproduce, release, perform, display, or disclose the data have expired or no longer apply.

D. Identification of Principal Rights. The allocation of principal rights shall be identified in each PP, using the categories list format provided below:

TYPE-PROPERTY NUMBER-RIGHTS ASSERTION

1. Application: provide date and type of application/title with brief description
2. Patent: provide patent no. and/or entity identifier/number
3. Rights: provide the type/category of right asserted

E. Marking of Data: Any Data delivered under this Agreement shall be marked with the following legend: "This data is being delivered as Category (insert category) Data, as defined in Agreement W911QY-21-9-0006. Use, duplication, or disclosure is subject to the restrictions as stated in Agreement W911QY-21-9-0006 between ABC and the Government."

In the event that ABC learns of a release to the Government of its unmarked Data that should have contained a restricted legend, ABC will have the opportunity to cure such omission going forward by providing written notice to the AO within six (6) months of the erroneous release.

F. Prior Technology

1. In the event it is necessary for ABC to furnish the Government with Data which existed prior to, or was produced outside of this Agreement, and such Data embodies trade secrets or comprises commercial or financial information which is privileged or confidential, and such Data is so identified with a suitable notice or legend, the Data will be maintained in confidence and disclosed and used by the Government and such Government Contractors or contract employees that the Government may hire on a temporary or periodic basis only for the purpose of carrying out the Government's responsibilities under this Agreement. Data protection will include proprietary markings and handling, and the signing of nondisclosure agreements by such Government Contractors or contract employees. ABC shall not be obligated to provide Data that existed prior to, or was developed outside of this Agreement to the Government. Upon completion of activities under this Agreement, such Data will be disposed of as requested by ABC.
2. Oral and Visual Information: If information which ABC considers to embody trade secrets or to comprise commercial or financial information which is privileged or confidential is expressly disclosed orally or visually directly to the Government, the exchange of such information must be memorialized in tangible, recorded form and marked with a suitable notice or legend, and furnished to the Government within thirty (30) calendar days after such oral or visual disclosure, or the Government shall have no duty to limit or restrict, and shall not incur any liability for any disclosure and use of such information. If the Government reasonably determines that the memorialization of the exchange is insufficiently detailed to enable it to identify the privileged or confidential information, ABC shall provide additional detail at the Government's request, subject to restrictions on use and disclosure.
3. Disclaimer of Liability: Notwithstanding the above, the Government shall not be restricted in, nor incur any liability for, the disclosure and use of:
 - a. Data not identified with a suitable notice or legend as set forth in this Article; nor
 - b. Information contained in any Data for which disclosure and use is restricted, if such information is or becomes generally known without breach of the above, is properly known to the Government or is generated by the Government independent of carrying out responsibilities under this Agreement, is rightfully received from a third party without

restriction, or is included in Data which ABC has furnished, or is required to furnish to the Government without restriction on disclosure and use.

Notwithstanding F.3.(a) of this Article above, if ABC cures the omission of the suitable notice or legend, the restrictions, and related liability for disclosure and use of such information shall apply after cure unless it is then unrestricted under F.3(b) of this Article above.

G. Copyright

ABC reserves the right to protect by copyright works developed under this Agreement. All such copyrights will be in the name of ABC or the author, as determined by ABC's policies. ABC hereby grants to the U.S. Government a non-exclusive, non-transferable, royalty-free, fully paid-up license to reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, for governmental purposes, any copyrighted materials developed (excluding Data) under this Agreement to which it owns the copyright, and to authorize others to do so.

H. Lower Tier Agreements

ABC shall include this Article, suitably modified to identify the parties, in all, subcontracts or lower tier agreements, regardless of tier, or experimental, developmental, or research work.

I. Survival Rights

Provisions of this Article shall survive termination of this Agreement.

ARTICLE XII: INTELLECTUAL PROPERTY RIGHTS

A. Background IP and Materials. The Awardee and the Government each retain any intellectual property (IP) rights to their own materials, data, technology, information, documents, or knowhow—or potential rights, such as issued patents, patent applications, invention disclosures, or other written documentation—that exist prior to execution of this Agreement or are developed outside the scope of this Agreement (Background IP). Additionally, neither Party to the Agreement will enter into an agreement with any third party whereby the third party will obtain rights in OTA Inventions or Study Data, as those terms are defined in this Agreement, absent the mutual consent of the Parties.

B. Awardee's Background IP. Awardee warrants that it has filed patent application(s) or is the assignee of issued patent(s) listed below which contain claims that are related to research contemplated under this Agreement. No license(s) to any of the following patent applications or issued patents shall be granted under this Agreement, and the application(s) and any continuing applications (except for continuing applications pursuant to this Agreement) are specifically excluded from the definitions of "OTA Invention" contained in this Agreement:

TITLE	PATENT #	Date of Patent	Assignee
NONE			

C. Patent indemnity. The Awardee shall indemnify the Government and its officers, employees and agents against liability, including costs, for actual or alleged direct or contributory infringement of, or

inducement to infringe, any United States patent, trademark or copyright, arising out of this Agreement, provided the Awardee is reasonably notified of such claims and proceedings.

ARTICLE XIII: TITLE AND DISPOSITION OF PROPERTY

A. Definitions

In this Article, "property" means any tangible personal property other than property actually consumed during the execution of work under this Agreement.

B. Title to Property

No significant items of property are expected to be acquired under this Agreement by ABC. Title to any item of property valued \$10,000 or less that is acquired by ABC in performance of the Prototype Project covered by this Agreement shall remain with ABC with no further obligation of the Parties unless otherwise determined by the AO. Should any item of property with an acquisition value greater than \$10,000 be required, ABC shall obtain prior written approval of the AO. Title to this property shall also remain with the America's Blood Centers. ABC shall be responsible for the maintenance, repair, protection, and preservation of all such property at its own expense. Property acquired pursuant to this clause shall not be deemed to be acquired in exchange for services in performance of the project, but shall be considered a government contribution to the project.

ARTICLE XIV: EXECUTION

This Agreement constitutes the entire agreement of the Parties and supersedes all prior and contemporaneous agreements, understandings, negotiations and discussions among the Parties, whether oral or written, with respect to the subject matter hereof. This Agreement may be revised only by written consent of America's Blood Centers and the ACC-APG-Natick Agreements Officer designated in this Agreement. By executing this agreement, America's Blood Centers affirms that it is a non-traditional defense contractor, small business, traditional defense contractor with significant non-traditional defense contractor participation or a traditional defense contractor providing a 1/3 cost share and, as a result, is eligible to be awarded this Agreement.

ARTICLE XV: MISCELLANEOUS

A. Security. The Recipient shall not develop and/or handle classified information in the performance of this Agreement. No form DD254 is currently required for this Agreement.

ABC is required to uphold continued compliance with the government approved version of its security program, as incorporated within the Project Plan – Attachment B. Changes without prior AO approval are prohibited.

B. Entire Agreement. This Agreement, inclusive of the proposal, proposal revisions, proposal attachments, and collaboration plan(s), constitutes the entire Agreement between the Parties concerning the subject matter hereof and supersedes any prior understandings or written or oral

Agreement relative to said matter.

C. Waiver of Rights. Any waiver of any requirement contained in this Agreement shall be by mutual agreement of the Parties hereto. Any waiver shall be reduced to a signed writing and a copy of the waiver shall be provided to each Party. Failure to insist upon strict performance of any of the terms and conditions hereof, or failure or delay to exercise any rights provided herein or by law, shall not be deemed a waiver of any rights of any Party hereto.

D. Liability. No Party to this Agreement shall be liable to the other Party for any property consumed, damaged, or destroyed in the performance of this Agreement, unless it is due to the negligence or willful misconduct of the Party or an employee or agent of the Party.

E. Non-Assignment. This Agreement may not be assigned by any Party except by operation of law resulting from the merger of a Party into or with another corporate entity.

F. Severability. If any clause, provision or section of this Agreement shall be held illegal or invalid by any court, the invalidity of such clause, provision, or section shall not affect any of the remaining clauses, provisions, or sections herein, and this Agreement shall be construed and enforced as if such illegal or invalid clause, provision, or section had not been contained herein.

G. Force Majeure. Neither Party shall be in breach of this Agreement for any failure of performance caused by any event beyond its reasonable control and not caused by the fault or negligence of that Party. If such a force majeure event occurs, the Party unable to perform shall promptly notify the other Party and shall in good faith maintain such partial performance as is reasonably possible and shall resume full performance as soon as is reasonably possible.

H. Foreign Access to Data. The Parties will comply with any applicable U.S. export control statutes or regulations in performing this Agreement.

I. Publicity. During the term of this Agreement, each Party will obtain the consent of the other Party before making any press releases or public statement pertaining to the Project or to this Agreement. This consent will not be unreasonably withheld. In addition, each Party will provide the other Parties sixty (60) days in which to review and comment on proposed scholarly publications or presentations. The publishing Party shall take into account any comments received, and shall remove any other Party's Confidential Information that appears in the publication.

J. Choice of Law. This Agreement and the resolution of disputes hereunder will be governed, construed, and interpreted by the statutes, regulations, and/or legal precedent applicable to the Government of the United States of America. Unless explicitly stated, the Parties do not intend that this Agreement be subject to the Federal Acquisition Regulation, or any other US Government grant or procurement regulation, either directly or indirectly or by operation of law. When a specific FAR or other procurement regulation requirement is incorporated by reference in this Agreement, the text of the clause alone will apply without application or incorporation of other provisions of these regulations.

K. Essential Critical Infrastructure. The Government expressly designates ABC, its members and subcontractors, for entire duration of this Agreement, as performing work on Essential Critical Infrastructure pursuant to the U.S. Department of Homeland Security guidance and applicable U.S. Department of Defense guidance. See, e.g., <https://www.dhs.gov/coronavirus/cybersecurity-and-critical-infrastructure>.

AWARD/CONTRACT		1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)		RATING	PAGE OF PAGES 1 8		
2. CONTRACT (Proc. Inst. Ident.) NO. W911QY2190006		3. EFFECTIVE DATE 30 Oct 2020		4. REQUISITION/PURCHASE REQUEST/PROJECT NO. 0011568081			
5. ISSUED BY W6QK ACC-APG NATICK DIVISION BLDG 1 GENERAL GREENE AVENUE NATICK MA 01760-5011		CODE W911QY	6. ADMINISTERED BY (If other than Item 5) See Item 5		CODE		
7. NAME AND ADDRESS OF CONTRACTOR (No., street, city, county, state and zip code) AMERICA'S BLOOD CENTERS ABC (b) (6) 1300 DIVISION RD STE 102 WEST WARWICK RI 02883-7558				8. DELIVERY <input type="checkbox"/> FOB ORIGIN <input checked="" type="checkbox"/> OTHER (See below)			
				9. DISCOUNT FOR PROMPT PAYMENT NET 30			
				10. SUBMIT INVOICES (4 copies unless otherwise specified) TO THE ADDRESS SHOWN IN:		ITEM	
CODE 3C8G9		FACILITY CODE					
11. SHIP TO/MARK FOR See Schedule		CODE	12. PAYMENT WILL BE MADE BY DEFENSE FINANCE AND ACCOUNTING SERVICE DFAS-INDY VP GFEB5 8899 E 56TH STREET INDIANAPOLIS IN 46249-3800		CODE	HQ0490	
13. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION: <input type="checkbox"/> 10 U.S.C. 2304(c)() <input type="checkbox"/> 41 U.S.C. 253(c)()			14. ACCOUNTING AND APPROPRIATION DATA See Schedule				
15A. ITEM NO.	15B. SUPPLIES/ SERVICES		15C. QUANTITY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT	
SEE SCHEDULE							
15G. TOTAL AMOUNT OF CONTRACT						\$29,999,587.25	
16. TABLE OF CONTENTS							
(X)	SEC.	DESCRIPTION	PAGE(S)	(X)	SEC.	DESCRIPTION	PAGE(S)
PART I - THE SCHEDULE				PART II - CONTRACT CLAUSES			
X	A	SOLICITATION/ CONTRACT FORM	1	X	I	CONTRACT CLAUSES	8
X	B	SUPPLIES OR SERVICES AND PRICES/ COSTS	2	PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACH.			
	C	DESCRIPTION/ SPECS/ WORK STATEMENT		J	LIST OF ATTACHMENTS		
	D	PACKAGING AND MARKING		PART IV - REPRESENTATIONS AND INSTRUCTIONS			
X	E	INSPECTION AND ACCEPTANCE	3	K	REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS		
X	F	DELIVERIES OR PERFORMANCE	4	L	INSTRS., CONDS., AND NOTICES TO OFFERORS		
X	G	CONTRACT ADMINISTRATION DATA	5 - 7	M	EVALUATION FACTORS FOR AWARD		
	H	SPECIAL CONTRACT REQUIREMENTS					
CONTRACTING OFFICER WILL COMPLETE ITEM 17 (SEALED-BID OR NEGOTIATED PROCUREMENT) OR 18 (SEALED-BID PROCUREMENT) AS APPLICABLE							
17. <input type="checkbox"/> CONTRACTOR'S NEGOTIATED AGREEMENT (Contractor is required to sign this document and return 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 terms listed above and on any continuation sheets. This award consummates the contract which consists of the following documents: (a) the Government's solicitation and your bid, and (b) this award/contract. No further contractual document is necessary. (Block 18 should be checked only when awarding a sealed-bid contract.)			
19A. NAME AND TITLE OF SIGNER (Type or print)				20A. NAME OF CONTRACTING OFFICER (b) (6)			
19B. NAME OF CONTRACTOR		19C. DATE SIGNED		20B. UNITED STATES OF AMERICA (b) (6)		20C. DATE SIGNED 30-Oct-2020	
BY _____ (Signature of person authorized to sign)				BY _____ (Signature of Contracting Officer)			

Section B - Supplies or Services and Prices

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0001	pOTA- Capability Expansion of CCP COST Development of a novel prototype process to expand the capabilities for the collection of COVID-19 Convalescent Plasma (CCP) in accordance with the Statement of Objectives, incorporated under Attachment A of the agreement. FOB: Destination PURCHASE REQUEST NUMBER: 0011568081 PSC CD: 6515		Lot		\$
				ESTIMATED COST	\$(b) (4)
000101	Funding for CLIN 0001 @ (b) (4) COST PURCHASE REQUEST NUMBER: 0011568081				\$0.00
	ACRN AA CIN: GFEB001156808100001			ESTIMATED COST	\$(b) (4) \$0.00

Section E - Inspection and Acceptance

INSPECTION AND ACCEPTANCE TERMS

Supplies/services will be inspected/accepted at:

CLIN	INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
0001	Destination	Government	Destination	Government
000101	N/A	N/A	N/A	N/A

Section F - Deliveries or Performance

DELIVERY INFORMATION

CLIN	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
0001	POP 31-OCT-2020 TO 30-OCT-2021	N/A	N/A FOB: Destination	
000101	N/A	N/A	N/A	N/A

Section G - Contract Administration Data

A. In no event shall any understanding or agreement, modification, change order, or other matter in deviation from the terms of this agreement between the Awardee and a person other than the Agreements Officer be effective or binding upon the Government. All such actions must be formalized by a proper contractual document executed by the Agreements Officer.

Government Representatives:

Other Transaction Agreements Officer (OTAO)

(b) (6)

Agreements Officer

ACC-APG-Natick

(b) (6)

Other Transaction Agreements Specialist (OTAS)

(b) (6)

Agreements Specialist

ACC-APG-Natick

(b) (6)

Other Transaction Agreements Officer Representative (OTAOR)

LTC (b) (6)

Agreements Officer Representative

Lead, Supply Chain Convalescent Plasma / HiG

Operation Warp Speed

(b) (6)

ACCOUNTING AND APPROPRIATION DATA

AA: 0212020202120400000664643255 S.0074658.5.19 6100.9000021001

COST CODE: A5XAH

AMOUNT: \$ (b) (6)

ACRN	CLIN/SLIN	CIN	AMOUNT
AA	000101	GFEB001156808100001	\$ (b) (6)

CLAUSES INCORPORATED BY FULL TEXT

252.232-7006 WIDE AREA WORKFLOW PAYMENT INSTRUCTIONS (DEC 2018)

(a) Definitions. As used in this clause—

“Department of Defense Activity Address Code (DoDAAC)” is a six position code that uniquely identifies a unit, activity, or organization.

“Document type” means the type of payment request or receiving report available for creation in Wide Area WorkFlow (WAWF).

“Local processing office (LPO)” is the office responsible for payment certification when payment certification is done external to the entitlement system.

“Payment request” and “receiving report” are defined in the clause at 252.232-7003, Electronic Submission of Payment Requests and Receiving Reports.

(b) Electronic invoicing. The WAWF system provides the method to electronically process vendor payment requests and receiving reports, as authorized by Defense Federal Acquisition Regulation Supplement (DFARS) 252.232-7003, Electronic Submission of Payment Requests and Receiving Reports.

(c) WAWF access. To access WAWF, the Contractor shall—

(1) Have a designated electronic business point of contact in the System for Award Management at <https://www.sam.gov>; and

(2) Be registered to use WAWF at <https://wawf.eb.mil/> following the step-by-step procedures for self-registration available at this web site.

(d) WAWF training. The Contractor should follow the training instructions of the WAWF Web-Based Training Course and use the Practice Training Site before submitting payment requests through WAWF. Both can be accessed by selecting the “Web Based Training” link on the WAWF home page at <https://wawf.eb.mil/>.

(e) WAWF methods of document submission. Document submissions may be via web entry, Electronic Data Interchange, or File Transfer Protocol.

(f) WAWF payment instructions. The Contractor shall use the following information when submitting payment requests and receiving reports in WAWF for this contract or task or delivery order:

a. Document type. The Recipient shall use the following document type: Invoice and Receiving Report (Combo)

b. Inspection/acceptance location. The Recipient shall select the following inspection/acceptance location(s) in WAWF, as specified by the contracting officer.

c. Document routing. The Recipient shall use the information in the Routing Data Table below only to fill in applicable fields in WAWF when creating payment requests and receiving reports in the system.

(3) Document routing. The Contractor shall use the information in the Routing Data Table below only to fill in applicable fields in WAWF when creating payment requests and receiving reports in the system.

Routing Data Table*

<i>Field Name in WAWF</i>	<i>Data to be entered in WAWF</i>
Pay Official DoDAAC	HQ0490
Issue By DoDAAC	W911QY
Admin DoDAAC**	W911QY
Inspect/Accept By DoDAAC	W56XNH
Ship To Code	W56XNH

Payee Information: As identified at the System for Award Management.

America's Blood Centers

Cage Code: 3C8G9

DUNS: 194910121

(4) Payment request. The Contractor shall ensure a payment request includes documentation appropriate to the type of payment request in accordance with the payment clause, contract financing clause, or Federal Acquisition Regulation 52.216-7, Allowable Cost and Payment, as applicable.

(5) WAWF point of contact.

1. The Recipient may obtain clarification regarding invoicing in WAWF from the following contracting activity's WAWF point of contact.

AOR: [REDACTED] (b) (6)

2. For technical WAWF help, contact the WAWF helpdesk at 866-618-5988.

(End of clause)

STATEMENT OF OBJECTIVES
for
Capabilities Expansion of Convalescent Plasma Collection for COVID-19

BACKGROUND/DESCRIPTION

Project Objective: Operation Warp Speed (OWS) has an urgent requirement for the development of a novel prototype process to expand the capabilities for the collection of COVID-19 Convalescent Plasma (CCP). The process shall include an innovative approach to increase donor activity, expand physical capacity, and contribute to a national reserve for CCP by collection of up to 15,000 units per week. The purpose of this prototype is to develop and deploy a rapid approach to increase efficient and effective collection, storage, and eventual distribution of CCP for use in transfusion and treatments to improve healthcare diagnosis for the general public.

On 24 August 2020, the U.S. Food and Drug Administration authorized emergency use of CCP, as it is one of the few proven treatments for COVID-19. Under Operation Warp Speed (OWS), the Department of Defense and the Department of Health and Human Services are interested in accelerating plasma collections within the United States from people who have recently fully recovered from COVID-19 and are symptom free for at least 14 days. The overarching goal of this program is to make COVID-19 convalescent plasma (CCP) available to all patients who need plasma therapies.

As previously stated, CCP is the plasma collected from the blood of people who have recently recovered from COVID-19 and remained symptom free for more than 14 days. Plasma collected from these donors typically contains antibodies that can potentially help fight COVID-19 in hospitalized patients. The desired end product of this effort will be a documented, proven, and replicable Operation Plan to collect up to 15000 units per week of CCP in order to establish a national reserve of 100,000 units (50,000 within supply chain, 50,000 in stockpile reserves). This reserve will provide the nation with the ability to respond swiftly to surges in cases of COVID-19 or other biological threats.

Background: In December 2019, a novel coronavirus now known as SARS-CoV-2 was first detected in Wuhan, Hubei Province, People’s Republic of China, causing outbreaks of the coronavirus disease COVID-19, which has since spread globally. The Secretary of Health and Human Services declared a public health emergency on January 31, 2020, under section 319 of the Public Health Service Act (42 U.S.C. 247d), in response to COVID-19. On March 1, 2020, the President of the United States, pursuant to sections 01 and 301 of the National Emergencies Act (50 U.S.C. 1601 et seq.) and consistent with section 1135 of the Social Security Act (SSA), as amended (42 U.S.C. 1320b-5), declared the COVID-19 outbreak in the United States as a national emergency.

Fourteen hotspots, called Metropolitan Statistical Areas (MSA), have been prioritized due to the high density of potential donors; communities hardest hit by the disease, and those deemed disadvantaged in COVID-19 medical treatment options. To stimulate plasma collection efforts within these select regions, collection capabilities need to be augmented in existing & new sites to accommodate an anticipated surge in CCP donations and demand for treatments.

The list of Metropolitan Statistical Areas (MSA) identified is as follows:

State	MSA
Arizona	Phoenix
California	Los Angeles
	Riverside
Florida	Miami (Ft. Lauderdale)
	Orlando
	Tampa
Georgia	Atlanta
Illinois	Chicago
Louisiana	New Orleans
New York	New York City
North/South Carolina	Charlotte-Concord-Gastonia
Texas	Dallas
	Houston
	San Antonio

REQUIREMENTS

The purpose of this prototype is to develop and deploy a rapid approach to increase efficient and effective collection, storage and eventual distribution of CCP for use in transfusion and treatments to improve healthcare diagnoses and contribute to the national reserve of CCP.

Technical Objectives: The potential solution should be designed to minimize risk associated with the expansion of non-profit plasma collection facilities. The Awardee shall identify & address the specific need(s) of each individual plasma collection facility to enable the rapid expansion of CCP collection. The USG has identified three (3) core Lines of Effort (LOE) necessary to achieve this goal:

- Donor Activation at the local level (to include but not limited to):
 - Localized marketing efforts
 - Antibody screening of potential donors
 - Methods to attract and retain donors (call centers, stipends/incentives, targeted outreach partnerships, etc.)
- Physical capacity, as needed:
 - Machines & Supplies

- Staffing
- Facilities (“pop up” locations or mobile units in areas experiencing a surge in COVID cases, with no access to formal donor centers).
- National Reserve:
 - This prototype shall allow blood centers to increase and maintain a reserve stock of CCP (at collection centers and centralized locations) which is above typical requirements and to make these therapeutic units available to the national healthcare system. Ownership, coordination, & management of reserve stocks shall remain with the respective blood centers.
 - Maintain a reserve inventory of 50K units, collectively, at blood collection centers across the nation for use in the supply chain. This stock shall be rotated, using “first-in, first-out” inventory methods, while maintaining a constant reserve inventory of no less than 50K units. Any additional reserve inventory shall be maintained at a centralized facility.
 - Maintain a reserve inventory of no more than 50K units at a centralized facility for contingency use.

Risk Management Objectives: The Awardee shall identify all anticipated project risks categorized as moderate or high and report them to the Government in accordance with reporting requirements (see “Deliverables” below). The Awardee shall manage all project risks using its in-house risk management capabilities, and report changes to all identified risks as they occur/arise.

Project Goals:

- Collection Capacity Expansion Support:
 - Arrange a partnership, consortium or other agreement establishing a working relationship with each blood center that will ensure all parties are working collaboratively towards the objectives of this project & agreement
 - The blood centers shall have the ability to collect 15,000 units of CCP per week, for a sustained period of 12 weeks or until the national reserve goal of 100,000 units is achieved.
 - Formulate and execute the capability to implement “resource sharing” across the national network of blood collectors in order to distribute units to meet demand in regional hotspots.
- Logistic Strategies and Operations: Awardee shall collect and oversee the supply chain of the national reserve with low and high titer units of CCP. The Awardee will utilize existing infrastructure and logistics systems to the extent practicable to facilitate the outcomes of this agreement.
- The prototype will be deemed successful whereas capabilities have been proven to successfully stimulate the collection of 15,000 units of CCP per week, for a sustained period of 12 weeks, or a national reserve goal of 100,000 units is achieved.

Deliverables:

- A final project report that provides an overview of the successes and failures experienced in the development of the prototype to enable the USG to prepare for future pandemic blood collection surge missions. The report shall be provided no later than 90 days after completion of the project.
- A detailed and replicable Operation Plan to collect up to 15,000 units per week of CCP or other blood products in order to establish a national reserve of 100,000 units. This plan will provide the nation with the ability to respond swiftly to surges in cases of COVID-19 or other biological threats the report shall be provided no later than 90 days after completion of the project and determination of the prototype's success by the Government.
- Monthly progress & expenditure reports.
 - No later than the 10th (tenth) day of each month during the Period of Performance, a monthly report shall be furnished which encompasses the previous month's notable progress, issues encountered, project risks identified and mitigation taken to reduce them, monthly expenditures & total project expenditures to date.

Project Management:

- The Awardee is responsible for the overall management of the project development and related project decisions. The Government will have continuous involvement with the Awardee through oversight and coordination, as specified below.
 - Monthly Status Meetings: The Awardee's Project Manager (PM), and Assistant Project Manager (APM) shall convene monthly with the Government Oversight Team to discuss the status of the project & review the submitted monthly report. This meeting shall coincide with the submission of the monthly reports, & should occur mid-month accordingly.
- The Awardee's organization shall be established with authority to effectively develop the Prototype. This organization shall become effective upon execution of an Agreement and its integrity shall be maintained until completion or acceptance of the effort by the Government. Key personnel shall be identified within the Awardee's project plan.
- The Awardee shall designate a Project Manager responsible for facilitating the communications, reporting, and meetings between the Parties. The Awardee shall also designate an alternate to the Project Manager, in case the primary Project Manager is unavailable.

Administration:

Agreement Type: Other Transaction Agreement (OTA)

Project Budget: \$30,000,000

Payment Terms: Cost Reimbursable

Estimated Period of Performance: 12 months, After Date of Award

Place of Performance: The work will be performed at various locations throughout the United States, as identified above.



America's Blood Centers[®]
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PROJECT PROPOSAL FOR EFFORTS TO EXPAND THE COLLECTION AND STOCKPILING OF COVID-19 CONVALESCENT PLASMA

Submitted by America's Blood Centers, CAGE code 3C8G9, DUNS #194910121

Submission Date: October 28, 2020

Re: OWS-BAA-20-01, SUPPORTING RESEARCH FOR THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES UNDER CONTRACTS, OTHER TRANSACTION AGREEMENTS, AND TECHNOLOGY INVESTMENT AGREEMENTS FOR THE TREATMENT AND PROTECTION FROM COVID-19

Authorized Point of Contact:

(b) (6)

Chief Executive Officer
America's Blood Centers
1717 K St. NW, Suite 900
Washington, DC 20001

Introduction

Thank you for the opportunity to support the expansion of COVID-19 Convalescent Plasma (CCP) collections on behalf of independent blood centers across the United States. The Food and Drug Administration (FDA) is permitting the use of investigational convalescent plasma under Emergency Use Authorization (EUA) for hospitalized patients. Through the blood donation process, CCP can be collected from a donor who has recovered from COVID-19 and then transfused to a patient fighting the virus.

America's Blood Centers (ABC) and Blood Centers of America (BCA), hereafter referred to as "The Team", propose to combine our individual corporate experience and capabilities to provide support and coordination services to Operation Warp Speed (OWS) for expanded collection and stockpiling of CCP. The Team recognizes the challenges involved in this contract; we are committed to providing OWS with high-quality service while at the same time providing the continuity of in-place, experienced staff.

ABC and BCA together represent 67 independent blood centers collecting over _____ of the U.S. blood supply and _____ of convalescent plasma. These blood centers collectively have the capacity to provide CCP for the duration of COVID-19, collecting nearly _____ doses of CCP and distributing over _____ doses to date, which has helped support patients fighting COVID-19. In addition, _____ doses have been sent to support The Armed Services Blood Program and _____ doses have been provided to support randomized clinical trials, (Investigational New Drug) INDs, and research. This number does not include the American Red Cross. CCP collections are currently outpacing distributions, allowing blood centers to start building a national stockpile of _____ units and growing.

Technical Objectives

ABC and BCA propose to support and coordinate the expansion of CCP collections for patient demand and stockpiling in accordance with the FDA "Recommendations for Investigational COVID-19 Convalescent Plasma" as revised on September 2, 2020. Through the coordinated effort, we will execute an (b) approach to increasing donor activity and support a _____ between OWS and individual blood centers (and vice versa) to ensure demand for CCP throughout the country is met.

We propose to accomplish the following:

1. Maximize funding to increase nation-wide collections of CCP to _____ doses per week and/or stockpiled doses;
2. Fund national and local targeted strategies to identify and drive additional CCP donors to blood centers;
3. Fund local targeted strategies to recruit and collect CCP donations in high seroprevalence geographic areas;
4. Fund targeted strategies to increase return/retention rate of existing CCP donors;
5. Fund initiatives to increase capacity in key blood center operational and manufacturing areas, maximizing CCP collections.

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Statement of Work/Lines of Effort (LOE)

ABC and BCA propose to accomplish the above Technical Objectives through the following Statement of Work. Funding will be distributed to blood centers that can demonstrate the ability to accomplish stated objectives in written proposals submitted to ABC, resulting in nation-wide collection of _____ units of CCP per week and/or a nation-wide stockpile of _____ doses of CCP. Examples of possible proposals that *could* be funded through this effort are attached.

I. Expand Convenience Factor for Donors in High Prevalence Areas

Overview: Research has demonstrated that individuals are more likely to donate blood when they can do so in a convenient location.¹ We propose to identify geographic areas with high seroprevalence rates, but without _____, to strategically operate CCP drives and/or _____ donation sites. Current OWS efforts with blood centers in select Metropolitan Statistical Areas (MSAs) have successfully engaged community partners in comprehensive activities to identify and recruit more donors. We believe expansion of these activities in conjunction with strategic location of donation opportunities will result in much higher rates of donation. Examples of proposed _____ that could be funded as part of this effort are attached.

Objectives:

- Host _____ events in high seroprevalence areas with support of community and civic partners;
- Maximize existing donor pool through targeted antibody testing;
- Stand up donation sites in high seroprevalence areas that currently lack _____

Expected impact on collections: Increase of _____ CCP doses per week for _____ weeks.

II. Blood Center Surge Capacity/Local Advertising/Donor Retention Activities

Overview: Recruitment and collection of recovered COVID-19 individuals requires extensive, personalized efforts on the part of blood centers. These efforts include donor outreach and qualification, public relations and marketing, and collections. We estimate that for every potential CCP donors, blood centers will be able to collect less than 200 doses due to stringent eligibility requirements (both CCP and regular blood donor requirements) and other factors. While blood centers have significant expertise in these areas, there is a need for increased funding to support expanded operations. As such, blood centers are seeking financial support to enhance and increase outreach efforts, commensurate with the increasing need for potentially lifesaving CCP units. Through this work, we aim to recruit an additional _____ eligible CCP donors per week. Each apheresis donation averages _____ doses of CCP.

¹ Schreiber, George & Schlumpf, Karen & Glynn, Simone & Wright, David & Tu, Yongling & King, Melissa & Higgins, Martha & Kessler, Debra & Gilcher, Ronald & Nass, Catharie & Guiltinan, Anne. (2006). Convenience, the Bane of our Existence, and Other Barriers to Donating. *Transfusion*. 46. 545-53. 10.1111/j.1537-2995.2006.00757.x.

Objectives: Funding in this category will be awarded to blood centers who can demonstrate the following needs and resulting increase of CCP donations:

- Increased donor incentives and other donor retention efforts in order to drive both initial

([REDACTED]

Expected impact on collections: Increase of CCP doses per week for 12 weeks.

III. Donor Motivations & Identification

Overview: As with regular blood donors, CCP donors are motivated by different factors, and recruitment efforts must be multi-faceted to respond to the personal motivation of each donor. Extrinsic motivation has been included in the above convenience factor section. In this section of the proposal, we seek to address intrinsic motivation.

Expected impact on collections: Increase of CCP doses per week for 12 weeks

Objectives:

- a. Expand the existing Thank the Donor program;
- b. Utilize

Thank-the-Donor Program

Thank-the-Donor (TtD) is an online, recipient and donor relationship management tool that enables patients who have received a blood transfusion to send a special message of appreciation to their blood donor(s) in an anonymous, user-friendly format. Through this novel web application, blood recipients can send special messages not only to their particular blood donors but also to blood center staff, hospital staff, and even vendors who have been part of the lifesaving chain. Recruiting donors and keeping them inspired can prove to be a challenge. Thank-the-Donor creates and emotional connection and reminder that a real person is on the receiving end of each donors' gift.

How it Works:

-


([REDACTED]

([REDACTED]

Results:

- Emails attached with Thank-the-Donor material or messages to Lapsed Donors has caused their return rate

ENHANCING YOUR COMMUNICAITON STRATEGY

LAPSED DONOR EMAIL	FOLLOW UP EMAIL
<p style="text-align: center;">Return Rate</p> 	

- Follow up emails to blood donors contain Thank-the-Donor materials or messages are more effective in securing a future donation appointment than without a short thank you example from a blood recipient to a donor

Program Objectives:

- Drive more CCP donors to blood centers;
- Increase the return rate of CCP;
- Targeted deployment of marketing resources through use of historic blood donor patterns within a center’s catchment area.
 - Initial focus on the initial MSA areas
 - Expand to rest of USA

IV. Surge Recruitment Efforts

Overview: Recruitment and collection of recovered COVID-19 individuals has become increasingly difficult throughout the pandemic due to a confluence of factors, including waning donor antibodies that necessitates the constant recruitment of new donors, “pandemic fatigue” within donor communities, low return rates of donors, high first time donor rates of CCP donors (have not previously donated blood so are less familiar with the process and require more time), changing federal regulatory compliance requirements, etc. Blood centers are also challenged in meeting the ongoing needs of the regular blood supply and are having to extend their staff

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operations to meet both missions. This section of the proposal

Technical Objectives & Approach

Phase 1: Identification and Planning, 1-2 Weeks

- Identify planned surge activities, goals, and funding needs by ABC member blood centers

Completion Criteria:

- Finalize plan for allocation of funding among blood centers

Phase 2: Development, 4-5 Weeks

-

Completion Criteria:

-

Phase 3: Execution, 12 Weeks

- Donor sites/events fully operational
- Advertising/marketing in key areas fully operational
- Deploy Thank-the-Donor programs to blood centers

Completion Criteria:

- Sustained collections units/week

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- Ability to stockpile units dependent on level of patient demand
- Successful adoption of peer-to-peer software
- Successful adoption of Thank-the-Donor programs
- Successful deployment of marketing assets by blood centers

Risk Management Objectives

ABC proposes to minimize risk to this project through the following objectives:

- Daily reporting from centers on CCP collections and distributions. This will allow for near real-time assessment of progress towards goals.
- Daily stockpile reporting at centers, surge storage centers, and BPL.
- Specific expansion and/or manufacturing goals for blood centers and bi-weekly reports on efforts towards those goals from blood centers receiving funding for these activities.
- Weekly communications with relevant federal agencies to determine likelihood of regulatory changes that could affect the prototype expansion plan.
- Assigned ABC and BCA staff to interface on technical and operational aspects of this prototype.

Deliverables

ABC proposes to provide Operation Warp Speed with the following deliverables in support and coordination services among blood collectors to include:

- Weekly collection and distribution files with all supporting documentation
- Weekly inventory reports by ABO type for units stockpiled

*All donor files will be maintained by individual blood collectors per FDA regulations. ABC/BCA will not play a supporting/coordinating role in this area.

Our approach to this project features:

- Coordination with select blood centers for collection expansion activities with the goal of weekly collections of (b) doses of CCP and/or a stockpile of (b) (4) doses;
- Management and reporting of national stockpile of CCP;
- Coordination with select blood centers for the manufacture of high-titer doses of CCP;
- Coordination, documentation, and facilitation of reimbursement to participating blood collectors for the expanded CCP collections and stockpiling;
- Coordination, documentation, and facilitation of reimbursement for stockpiling of excess CCP;
- Other support and coordinating work as needed to support the Technical Objectives.

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

Supporting documentation for CCP units collected, stockpiled, and/or distributed will be retained by BCA. See Appendix for a sample of the supporting documentation. Blood centers will release

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product based on FDA recommendations; ABC/BCA will not be involved in this activity.

Administrative

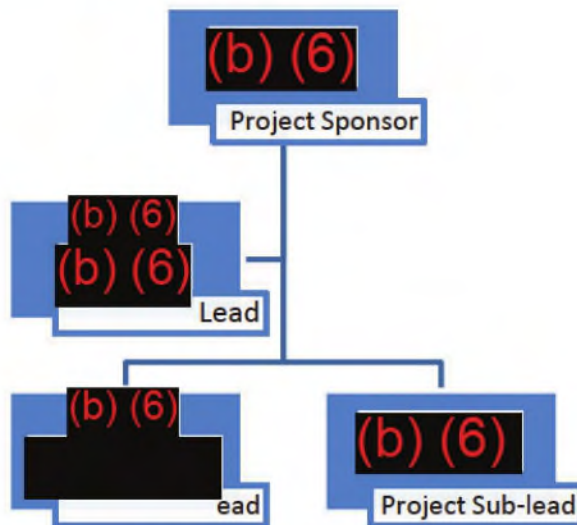
ABC is requesting a administration fee for the scope of work executed as part of the proposed contract. This fee encompasses coordination with blood centers, collection and analyzing collection and distribution reports, execution of national initiatives to drive donor engagement, management of the national stockpile, and invoicing and distribution of payment to ABC/BCA centers. This rate is commensurate and competitive with other national brokers for blood components and includes ongoing support of all aspects of this proposal. The administrative fee will be billed as part of invoices sent to OWS for work conducted by blood centers as well as any incurred by ABC and/or BCA.

Security

A copy of the BCA security program is attached to this proposal.

. We believe that government requirements not included in this program are not applicable to this contract given the nature of the work being conducted.

Project Management



Contact Information and Qualifications:

Project Sponsor: (b) (6) (b) (6), America's Blood Centers,

(b) (6) was named chief executive officer of America's Blood Centers (ABC) in April 2018 after joining ABC in 2016 as Chief Administrative Officer. A recognized leader in healthcare association management and advocacy, (b) (6) leads ABC's strategy development and advocacy work before federal legislators, regulators, and strategic partners. In previous positions, (b) (6) directed multi-faceted national advocacy campaigns to achieve significant legislative and

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regulatory victories and managed nationwide grassroots programs to execute on targeted advocacy goals to key members of Congress and regulatory agencies. (b) (6) brings significant expertise in representing the views of associations before members of Congress and congressional staff.

Project Lead: (b) (6), America's Blood Centers,

(b) (6) leads the development of public policy priorities impacting ABC members and advocacy before federal legislators, regulators, and strategic partners. Previously (b) (6) worked at the National Rural Health Association on a broad array of health care issues impacting rural Americans achieving substantial legislative and regulatory victories positively impacting access to care in rural America. She previously worked as a legislative assistant to (b) (6) while the chair of health subcommittee for the Ways and Means Committee, where she handled a variety of health care issues with a focus on Medicare policy. She also worked as a health policy fellow at the Heritage Foundation. (b) (6) earned a J.D. from Michigan State University College of Law and bachelor's degrees in mechanical engineering from Lake Superior State University and psychology from Central Michigan University.

Project Sub-Lead: (b) (6),

(b) (6) has more than 20 years of leadership experience. After serving as an infantry officer in the US Army and Army Reserves for eight years after college, he distinguished himself in various sales, marketing and general management roles in several large companies including Baxter, McKesson and Cardinal, as well as several smaller medical products firms including Orasure, HemCon and InstruMed.

Accounting Lead: (b) (6)

(b) (6) serves as the chief accounting executive at BCA, responsible for the production of financial reports, maintenance of accounting records and a comprehensive set of controls. She manages the accounting services that support group sales, and spearheads the periodic and highly-praised Participant Activity Report (PAR) project, providing financial metrics to individual members.

Subcontract:

ABC proposes to subcontract _____ aspects of this proposal to Blood Centers of America (BCA). Attached to this proposal is additional information regarding BCA's registration as a Federal Contractor (System For Award Management - SAM) and CAGE Code Number and DUNS Number. Also attached is an HHS Contract evaluation summary (CPAR) stating that BCA performed

ABC proposes to subcontract a portion of the proposed work to BCA in order to

Conflict of Interest Statement

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I, Katherine Fry, certify that there is no conflict of interest in the performance of this project.

Past Performance

America's Blood Centers (ABC) and Blood Centers of America (BCA) are currently engaged in an active contract with the Biomedical Advanced Research and Development Authority (BARDA) in support of the collection of distribution of CCP. This contract dated 5/22/2020, has been successfully executed and resulted in the collection of more than (b) doses of CCP. This model was also done successfully for ABC/BCA centers under a previous Department of Health and Human Services (HHS) contract in 2016 to provide blood products to Puerto Rico during ZIKA. We believe this proven relationship will again lead to timely and successful coordination of CCP.

Project Proposal Budget

Overview: See attachment for specific breakdown

Scope of Work	Direct Charges
Expanded collection events and sites	(b) (4)
Blood Center Capacity Building	
National Donor Identification	
Surge Recruitment	
Admin Fees	
TOTAL	(b) (4)

Attachments:

- Budget Proposal
- BCA registration as a Federal Contractor (System For Award Management - SAM) and CAGE Code Number and DUNS Number
- HHS Contract evaluation summary (CPAR) stating that BCA

- BCA Information Systems Security Plan
- Sample project proposal –
- Sample project proposal –

Budget Category	Direct Charges	Description	Scope
Expanded collection events and sites	B(4) \$	Monthly rent for short term leases	B(4)
Expanded collection events and sites	B(4) \$	Event site fees and build out if needed	B(4)
Expanded collection events and sites	B(4) \$	Donor incentives/management	B(4)
Expanded collection events and sites	B(4) \$	Donor testing and processing costs	B(4)
Expanded collection events and sites	B(4) \$	Donor Marketing/Advertising	B(4)
Expanded collection events and sites	B(4) \$	Labor	B(4)
TOTAL			
Blood Center Capacity Building	B(4) \$	Labor	B(4)
Blood Center Capacity Building	B(4) \$	Advertising	B(4)
SUBTOTAL	B(4) \$		B(4)
National Donor Identification & Asset Development	B(4) \$	Labor	B(4)

National Donor Identification & Asset Development	B(4) \$	database expansion and data assessment	B(4)
National Donor Identification & Asset Development	B(4) \$	Blood Center License Fees for Thank-the-Donor.	B(4)
SUBTOTAL	B(4) \$		B(4)
Surge Recruitment	B(4) \$		B(4)
	B(4) \$		B(4)
PROJECT PROPOSAL SUBTOTAL	B(4) \$		B(4)
ABC/BCA Admin Fees	B(4) \$		project B(4) management of
PROJECT TOTAL	B(4) \$		B(4)

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BCA Information Systems Security

b(4)

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