

**OTHER TRANSACTION AUTHORITY  
FOR PROTOTYPE  
AGREEMENT**

**BETWEEN**

**JOHNS HOPKINS UNIVERSITY (Awardee)  
1101 E. 33rd Street/ Suite B001  
Baltimore, MD 21218**

**And**

**NATICK CONTRACTING DIVISION (Government)  
110 Thomas Johnson Drive, Suite 240  
Frederick, MD 21702**

**Effective Date: June 8, 2020**

**Agreement No.: W911QY-20-9-0012**

**Total Amount of the Agreement: (b) (6)**

**Awardee**

**(b) (6)**

**Signature**

**(b) (6)**

**Printed Name**

**(b) (6)**

**Title**

**6-8-2020**

**Date**

**Government**

**(b) (6)**

**Signature**

**(b) (6)**

**Printed Name**

**Agreements Officer**

**Title**

**8 June 2020**

**Date**

## ACCOUNTING AND APPROPRIATION DATA

(b) (4)

AMOUNT: (b) (4)

(b) (4)

### ARTICLE 1. Scope.

A. 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.

B. (b) (4)

In consideration for Government funding under this Agreement, the Awardee will provide research and development directed at the Prototype as described in the Awardee’s Statement of Work, which is incorporated herein and attached hereto as Appendix A.

C. Pursuant to 10 USC 2371b, the Government may pursue production of any prototype successfully developed under this Agreement through a follow-on contract or transaction with the participants to this Agreement. No follow-on production is anticipated.

D. The Parties intend that the development hereunder is to be performed in response to the Secretary of Department of Health and Human Services’ Declaration effective February 4, 2020 with respect to authorized medical countermeasure against COVID-19 under the Public Readiness and Emergency Preparedness Act (“PREP Act”).

### ARTICLE 2. Term and Termination.

A. Term: The Term of this Agreement commences upon the Effective Date and extends through May 31, 2021. A transaction for a prototype project is complete upon the written determination of the appropriate official for the matter in question that efforts conducted under a Prototype OT: (1) met the key technical goals of a project; (2) satisfied success metrics incorporated into the Prototype OT; or (3) accomplished a particularly favorable or unexpected result that justifies the transition to production.

B. Termination for Convenience: The Government may terminate this Agreement for any or no reason by providing at least ninety (90) calendar days’ prior written notice to the Awardee. In the event this Agreement is terminated, the Government agrees to reimburse Awardee for all costs incurred up to the point of termination, including all non-cancellable commitments made prior to receipt of the termination notice and also costs incurred as a result of such termination, plus a pro rata share of the fixed fee.

C. The Government and Awardee will negotiate in good faith a reasonable and timely adjustment of all outstanding issues between the Parties as a result of termination by the Government for convenience, consistent with the terms of this Agreement.

D. Termination for Cause: If the Awardee materially fails to comply with the provisions of this Agreement, the Other Transaction Agreement Officer (OTAO), after issuance of a cure notice and failure of the Awardee to cure the defect within thirty (30) calendar days or the time allowed by the OTAO after Awardee's receipt of the cure notice, whichever is longer, may immediately terminate this Agreement or otherwise specify an effective date for such termination. In the event that this Agreement is terminated for cause, the Government agrees to reimburse the Awardee for costs incurred plus a portion of the fixed fee based on work product that has been completed and accepted in accordance with the Statement of Work.

If this Agreement is terminated for Cause, Awardee will grant the Government a non-exclusive, paid up, perpetual license to technologies developed under this Agreement and any subject to Awardee's legal ability to do so, Background IP related to technologies developed up to Termination, including patents and documentation necessary for the purpose of developing the Prototype. The Awardee shall provide the U.S. Government or its designee with a non-exclusive, paid up, license to all Background IP (defined in Article 10) that relates to technology provided up to Termination to permit the U.S. Government to pursue commercialization of the technology with a third party, on terms to be agreed between the Parties and subject to rights granted or held by third parties. The terms of this section and the obligations herein will be included in any exclusive license given by the Awardee to a third party for any intellectual property covered by this Agreement, on terms to be agreed between Awardee and such third party. This clause will survive the acquisition or merger of the Awardee by or with a third party.

E. Notwithstanding this Article 2.C, the Government's rights and Awardee's obligations under this paragraph will cease to exist if the Government terminates this Agreement for any reason other than for Awardee's failure to materially comply with the terms of this Agreement.

F. Survival: In the event of Termination, all rights, obligations, and duties hereunder, which by their nature or by their express terms extend beyond the expiration or termination of this Agreement, including but not limited to warranties, indemnifications, intellectual property (including rights to and protection of Intellectual Property and Proprietary Information), and product support obligations shall survive the expiration or termination of this Agreement.

### **ARTICLE 3. Project Management.**

A. Program Governance: The Awardee is responsible for the overall management of the project development program and related program decisions. The Government will have continuous involvement with the Awardee. The Awardee shall provide access to project results in accordance with the Awardee's Project Timeline located in Appendix A.

B. Project Managers: The Awardee and the Government will each designate a Project Manager responsible for facilitating the communications, reporting, and meetings between the Parties. Each Party will also designate an alternate to the Project Manager, in case the primary Project Manager is unavailable. See Project Manager/Alternate Project Manager point of contact information for each respective party below:

Awardee Project Managers:

Primary Project Manager	Alternate Project Manager
(b) (6)	

Government Project Managers:

Primary Project Manager:	Alternate Project Manager:
(b) (6)	

C. Key Personnel: The Awardee's organization shall be established with authority to effectively develop the Prototype. This organization shall become effective upon execution of this Agreement and its integrity shall be maintained until the Prototype is delivered to and accepted by the Government. The key personnel listed in Appendix C - Personnel 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 OTAO. 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 4. 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 Agreement Officer be effective or binding upon the Government. All such actions must be formalized by a proper contractual document executed by the Agreement Officer.

**Government Representatives:**

Other Transaction Agreements Officer (OTAO)

(b) (6)

ACC-APG-Fort Detrick  
 110 Thomas Johnson Dr.  
 Frederick, M (b) (6)

Other Transaction Agreement Specialist (OTAS)

(b) (6)

ACC-APG-Fort Detrick  
 110 Thomas Johnson Dr.  
 Frederick, MD 21702  
 (b) (6)

**Government Agreements Officer Representative:**

(b) (6)  
Senior Scientists  
JPM CBRN Medical  
JPEO CBRND  
Frederick, MD  
(b) (6)

**Awardee Representatives:**

(b) (6)

Technical / Programmatic:

(b) (6)

**ARTICLE 5. Performance Objectives and Changes.**

A. Statement of Work (SOW): The SOW, Appendix A, describes the scope of activities that will be undertaken by the Awardee to achieve the objective.

B. Recommendations for Modifications: At any time during the term of this Agreement, progress or results may indicate that a change in the SOW would be beneficial to the project objectives. Recommendations for modifications, including justifications to support any changes to the SOW, will be documented in a letter and submitted by Awardee to the GPM with a copy to the OTA0. 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 OTA0 and made part of this Agreement. Any modification to this Agreement to account for recommended changes in the SOW or Cost and Fee will be considered a supplemental agreement.

C. Review of Recommendations: The OTA0 will be responsible for the review and verification of any recommendations to revise or otherwise modify the Agreement, the SOW, the Cost and Fee, 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 OTA0.

F. Modification Communications: No other communications, whether oral or in writing, that purport to change this Agreement are valid.

G. Government Property: If applicable, terms and conditions applicable to Government Property shall be incorporated through Appendix D.

H. Disputes: For any disagreement, claim, or dispute arising under this Agreement, the parties shall communicate with one another in good faith and in a timely and cooperative manner. Whenever disputes, disagreements, or misunderstandings arise, the parties shall attempt to resolve the issue by discussion and mutual agreement as soon as practicable. Failing resolution by mutual agreement, the aggrieved party shall request a resolution in writing from the OTA0. The OTA0 will review the matter and render a decision in writing. Any such decision is final and binding. In the event of a decision, within (60) calendar days of the referral for review (or such other period as agreed upon by the parties), either party may pursue any right or remedy provided by law in a court of competent jurisdiction as authorized by 28 U.S.C. 1491. Alternately, the parties may agree to explore and establish an Alternate Disputes Resolution procedure to resolve this dispute.

## **ARTICLE 6. INSPECTION/ACCEPTANCE**

A. Inspection: The Government has the right to inspect and test all work called for by the agreement, to the extent practicable at all places and times, including the period of performance, and in any event before acceptance. Acceptance shall be defined as performed in accordance with the Statement of Work. 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. If the Government performs any inspection or test on the premises of the Awardee, the Awardee shall furnish, at no increase in agreement price, all reasonable facilities and assistance for the safe and convenient performance of these duties. Except as otherwise provided in the Agreement, the Government shall bear the expense of Government inspections or tests made at other than the Awardee's premises.

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.

C. Unless otherwise provided in the agreement, the Government shall accept work as promptly as practicable after delivery, and work shall be deemed accepted 90 days after delivery, unless accepted earlier. At any time during contract performance, but no later than 6 months after acceptance of all of the end items (other than designs, drawings, or reports) to be delivered under the agreement, the Government may require the Awardee to

reasonably cure work not meeting agreement requirements as identified in the Statement of Work. Time devoted to the replacement or correction of such work shall not be included in the computation of the above time period. Except as otherwise provided in paragraph (E) below, the cost of replacement or correction shall be determined as allowable as specified in the Agreement, but no additional fee shall be paid. The Awardee shall not tender for acceptance work required to be replaced or corrected without disclosing the former requirement for replacement or correction, and, when required, shall disclose the corrective action taken.

D. This clause shall apply in the same manner to a corrected or replacement end item or components as to work originally delivered.

E. If the Awardee fails to proceed with reasonable promptness to perform required replacement or correction resulting from fraud, lack of good faith, willful misconduct, or the conduct of one or more of the Awardee's employees, the Government may, by agreement or otherwise, perform the replacement or correction, and charge to the Awardee any increased cost, or make an equitable reduction in any fixed fee paid or payable under the agreement; Or, require delivery of any undelivered articles and shall have the right to make an equitable reduction in any fixed fee paid or payable under the agreement.

F. Failure to agree on the amount of increased cost to be charged the Contractor or to the reduction in fixed fee shall be a dispute.

## **ARTICLE 7. Financial Matters**

This Agreement is an expenditure type Other Transaction Authority agreement. The Contract Line Items (CLINs) provided under this Agreement are intended to compensate the Awardee on a cost plus fixed fee basis for performance under this Agreement as follows:

A. Payment. The Awardee shall be paid for each invoice submitted by the Awardee and approved by the OTA AOR in accordance with the schedule set forth in Appendix B. The schedule is predicated upon the Government's fiscal year, which ends on September 30 and begins on October 1 of the prior calendar year.

B. Obligation. Under no circumstances shall the Government's financial obligation exceed the amount obligated in this Agreement or by amendment to the Agreement. The amount of Government funds obligated by this Agreement and available for payment is set forth on page 1, Line of Accounting and Appropriation and/or identified in separate modifications. The Government intends to incrementally fund this agreement.

C. The Government is not obligated to provide payment to the Awardee for amounts in excess of the amount of obligated funds allotted by the Government.

D. The Government shall pay the Awardee, upon submission of proper invoices as specified in appendix B. Payments will be made within thirty (30) calendar days of receipt of a request for payment.

### **E. WIDE AREA WORKFLOW PAYMENT INSTRUCTIONS (MAY 2013)**

(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.

- (b) 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.
- (c) WAWF access. To access WAWF, the Awardee 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.
- (d) WAWF training. The Awardee 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 Awardee must use the following information when submitting payment requests and receiving reports in WAWF for this contract/order:

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

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

(3) Document routing. The Awardee 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	<b>HQ0490</b>
Issue By DoDAAC	<b>W911QY</b>
Admin DoDAAC	<b>W911QY</b>
Inspect By DoDAAC	<b>W56XNH</b>
Ship To Code	<b>W56XNH</b>



(4) Payment request and supporting documentation. The Awardee 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.

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

PGPM

(b) (6)  
OTOA

(b) (6)  
OTAS

(g) WAWF point of contact.

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

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

(End of Clause)

F. 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 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 8. Report and Data Requirements**

A deviation from any deadline specified will be at the mutual agreement of the parties.

### **Weekly Teleconferences and Communication**

Awardee shall conduct weekly teleconferences with the Government throughout the performance of the Agreement to discuss tasks accomplished and direction for the upcoming tasks. The Government anticipates reducing the teleconferences once enrollment executes and again after completion of the trial. Awardee shall provide agendas and read-ahead material as required two days prior to the meetings and shall provide minutes of each meeting to the Government. Awardee shall include key subcontractors as attendees at these teleconferences when applicable. The Awardee shall provide meeting minutes within three (3) business days after each formal scheduled meeting/teleconference conducted with MCS/JPEO.

### **Quarterly Progress Reports**

The Awardee shall submit a Quarterly Progress report within thirty (30) calendar days after the end of each quarter of performance. The Quarterly Progress report shall contain the technical progress made during the previous quarter and the updated resource loaded Integrated Master Schedule (IMS) in Microsoft Project format. The schedule update shall include the explanation for any changes in the schedule, and drivers for the changes, as applicable. The report should also address any concerns that would impact the performance, schedule, or cost planned for the effort. The Awardee shall report risk matrix format to include risk mitigation strategies. Note: Any identified changes require formal notification to the OTA in accordance with the Agreement provisions.

In addition, the Quarterly Progress Report shall contain regular status updates of all Intellectual Property (IP) license(s) related to the effort to ensure that all license(s) are in good standing as the project progresses. In the event of any change in IP license(s) status or potentially imminent change in status, the Awardee shall immediately contact the OTA and GPM in writing.

The Government will have ten (10) calendar days to respond to the report with any comments and the Awardee will have an additional fifteen (15) calendar days to revise the deliverable or respond to those comments.

### **Quarterly Financial Status Report**

The Awardee shall submit a Quarterly Financial Status Report no later than thirty (30) calendar days after the end of each quarter of performance. The Government will have

ten (10) calendar days to respond to the report with any comments and the Awardee will have an additional fifteen (15) calendar days to revise the deliverable or respond to those comments. Reports will cover work performed every three (3) months for the duration of the Period of Performance (PoP).

In addition, the Quarterly Financial Status Report shall include quarterly expenditure forecasts with both the quarterly planned accrual and the cumulative total. Expenditure forecast submissions shall include analysis of the cost drivers for Estimate to Complete changes, if any, from the previous projection. The Awardee shall provide all submissions in Excel format, including all formulas.

### **Expenditure Forecasts**

The Awardee shall submit the first expenditure forecast within thirty (30) calendar days after receiving the project award. An updated forecast shall be submitted within twenty (20) calendar days of any project modifications that modify the PoP or the cost of the prototype. Expenditure forecast submissions shall include analysis of the cost drivers for Estimate to Complete changes, if any, from the previous projection. The Awardee shall provide all submissions in Excel format, including all formulas.

#### Final report

A Final Report shall be prepared at the end of the effort by the Awardee. The Final Report shall narrate a complete summary of the project execution and associated results obtained. The narration will include outstanding problems and their potential solutions, problems solved during the course of the agreement, and the solutions to the solved problems. The Final Report shall demonstrate how the prototype was developed and advanced.

The Awardee shall submit a Draft Final Report by the forty-fifth (45th) calendar day following the end of the project. The Government shall provide comments to the Awardee by the thirtieth (30th) calendar day following receipt of the Awardee's Draft Final Report. The Awardee shall submit the Final Report on the thirtieth (30th) calendar day after receipt.

#### Ad Hoc Meetings

In addition to the monthly meetings and written quarterly program updates, additional ad hoc meetings to address specific issues or to convey time-sensitive updates or scientific data related to the program will be held as reasonably necessary.

#### Patents - Reporting of Subject Inventions

For purposes of this paragraph, "Subject Invention" is defined as any invention, discovery, or improvement of the Awardee, whether or not patentable, that are conceived of or first actually reduced to practice in the performance of work under this Agreement. The Awardee shall report any OTA Inventions in accordance with the terms and conditions of this Other Transaction Agreement (OTA).

#### Regulatory Documentation and Technical Data Packages

The Awardee shall work in consultation with the Government Regulatory and Quality Affairs staff for the development of all regulatory submission packages to the FDA and include Government Regulatory and Quality Affairs staff in all formal discussions with the FDA. The Awardee shall provide the Government copies of all technical data generated by the Awardee prior to and during performance of the project, necessary to pursue FDA approval and notify the Government of FDA decisions as these take place.

If applicable, the Awardee shall prepare an IND/BLA in the Electronic Common Technical Document (eCTD) format for submission to the FDA and the Government. The awardee shall submit all pre-IND, IND, pre-EUA, and/or BLA report submissions to the AOR. The Awardee shall provide all written communications to and/or from the FDA to the Government as it takes place. The Awardee shall courtesy copy the AOR on all email traffic to the FDA and will forward all emails received from the FDA to the AOR. Meeting minutes will be forwarded to the AOR within seven (7) calendar days of the meeting or teleconference.

## Miscellaneous Data Submissions

Awardee must submit to the Government all Point Papers, Briefings, Technical Performance Plans (TPP), Program Development Plans (PDP), Regulatory Strategy, Technology Transfer Report and Gap Analysis, Formulation Development, Feasibility and Optimization Reports, United States Army Medical Research and Material Command Animal Care and Use Review Office (USAMRMC ACURO) Approvals, Human Resources Operations Branch (HROB) Approvals, Technical Presentations and Publications, and any formal technical reports that have been prepared for eventual submission to FDA or other regulatory agencies. Examples include the following reports related to: pharmaceutical development, manufacturing development, manufacturing validation, completed batch records, certificates of analysis, analytical development and validation, drug substance and product stability, nonclinical testing, and clinical testing.

## Work Breakdown Structure

Three-level WBS with costs and schedule (top level is program, level two (2) is phase, level three (3) are major tasks). For WBS level two (2), show breakdown for labor, material, and other indirect costs.

WBS shall be updated annually or thirty (30) calendar days after a Statement of Work modification. Government review/approval is fifteen (15) calendar days after receipt of first submittal. Provide changes to draft within ten (10) calendar days of such request. Provide final document within ten (10) calendar days after approval of changes is received.

## Integrated Master Schedule

The Awardee shall provide within thirty (30) calendar days after project award an IMS in Microsoft Project format. Any updates to the IMS shall be included in the monthly progress reports.

Submission shall be thirty (30) calendar days after the end of each month of performance. The Government will have ten (10) calendar days to respond to the report with any comments and the performer will have an additional fifteen (15) calendar days to revise the deliverable or respond to those comments.

## Incident Report

The Awardee shall report any incident to the Government that could result in more than a one month delay in schedule from the most recent IMS critical path delivered to the Government. Telephonically contact the GPM within one day of incident. A written summary report shall be submitted within three (3) business days of an incident, to include, what happened, what was the impact, if there are any available corrective actions and a time line for when the corrective actions would be in place.

## **ARTICLE 9. Intentionally Deleted.**

## **ARTICLE 10. Intellectual Property Rights**

A. Background IP and Materials. The Awardee and the Government each retain any rights to intellectual property (IP) that exist prior to execution of this Agreement or are developed outside the scope of this Agreement (Background IP). Additionally, no party to this Agreement will enter into an agreement with any contract manufacturer or other 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 to the awarded contract.

B. Awardee's Background IP. Awardee affirms that it has no trade secrets, patents, or patent applications related to research contemplated under this Agreement that are not already licensed to the U.S. Government with Unlimited Rights through FAR based contracts. Should Awardee become aware of any Awardee IP related to the research and development under this Agreement that is not already licensed to the U.S. Government (Unforecasted Background IP), Awardee shall submit a table listing such Unforecasted Background IP to the Government within thirty (30) days of such knowledge. No license to Unforecasted Background IP shall be granted under this Agreement, and such technologies are specifically excluded from the definitions of "OTA Invention" contained in this Agreement. The Government shall receive an Unlimited Rights license to the technologies developed pursuant to this Agreement.

C. Authorization and Consent for Non-commercial Products. The Government authorizes and consents to all use and manufacture, in performance of this Agreement, of any invention described in and covered by a United States patent, except for deliverables under this Agreement that are commercially available to the public by the Awardee

D. Patent Indemnity for Commercial Products. Awardee shall indemnify the Government and its officers, employees and agents against liability, including costs, for actual negligent or willful infringement of, or inducement to infringe, any United States or foreign patent, trademark or copyright, arising out of Awardee's own commercially available deliverables under this Agreement, provided the Awardee is notified within two months of such claims and proceedings. Each Party will advise the other Party promptly and in reasonable written detail, of each claim or lawsuit of patent infringement based on the performance of this Agreement. When requested by either Party, all evidence and information in possession of the Party pertaining to such claim or lawsuit will be provided to the other at no cost to the requesting Party.

E. Patent Prosecution. Awardee agrees to take responsibility for the preparation, filing, prosecution, and maintenance of any and all patents and patent applications listed as Awardee Background IP that are relevant to work performed under this Agreement. Upon request by the Government, Awardee shall keep the Government reasonably advised on the status of Awardee Background IP by providing a report on the status of Awardee Background IP. Prior to acting on a decision by Awardee to abandon or not file in any country a patent or patent application covering an OTA Invention, which is defined below, Awardee shall so inform the Government in a timely manner to allow Awardee to thoughtfully consider the Government's comments regarding such a proposed decision. Nothing in this ARTICLE shall restrict the Government in its preparation, filing, prosecution and maintenance of a patent or patent application covering an OTA Invention made solely by a Government employee or employees.

F. Patent Enforcement. Awardee will have the first option to enforce any patent rights covering an OTA Invention owned jointly by the Parties or solely by Awardee, at Awardee's expense. If Awardee chooses not to exercise this option, the Government may enforce patent rights covering a joint OTA Invention only with Awardee's prior written approval.

G. Ownership. Ownership of any invention, regardless of whether it is not patentable, held as a trade secret or is patentable under U.S. patent law that is conceived or first reduced to practice under this Agreement (OTA Invention) will follow inventorship in accordance with U.S. patent law. The Bayh-Dole Act, 35 U.S.C. §§ 200-212 does not apply to this Agreement and, as such, title to inventions will accrue to the inventor or inventor-organization. The Parties represent and warrant that each inventor will assign his or her rights in any such inventions to his or her employing organization. If either an Awardee employee or a Government employee makes a sole OTA Invention, the entire rights to that OTA Invention will be respectively assigned

to the Awardee or the Government. If an Awardee employee and a Government employee are joint inventors of an OTA invention, it will be owned jointly by the Awardee and the Government.

H. Patent Applications. Irrespective of any Disclosure of Information clauses in this Agreement the Parties will respectively have the option to file a patent application claiming any OTA Invention made solely by their respective employees. The Parties will consult with each other regarding the options for filing a patent application claiming a joint OTA Invention. Within two months of being notified of the discovery of an OTA invention or filing a patent application covering an OTA Invention, each Party will provide notice of such discovery or filing to the other Party. The Parties will reasonably cooperate with each other in the preparation, filing, and prosecution of any patent application claiming an OTA Invention. Any Party filing a patent application will bear expenses associated with filing and prosecuting the application, as well as maintaining any patents that issue from the application, unless otherwise agreed by the Parties.

I. Licenses. Upon the Awardee's request, the Government agrees to enter into good faith negotiations with the Awardee regarding the Awardee's receipt of a nonexclusive commercialization license covering the Government's interest in any OTA Invention made in whole or in part by a Government employee. Any OTA Invention made by a Awardee employee is subject to a nonexclusive, nontransferable, irrevocable, paid-up license for the Government to practice and have practiced the OTA Invention.

J. Executive Order No. 9424 of 18 February 1944 requires all executive Departments and agencies of the Government to forward through appropriate channels to the Commissioner of Patents and Trademarks, for recording, all Government interests in patents or applications for patents.

## **ARTICLE 11. Data Rights and Software.**

A. All data generated in connection with the performance of the studies under this Agreement, or that arises out of the use of any materials or enabling technology provided or used by the Awardee in the performance of this Agreement, other Awardee materials or Awardee confidential information, whether conducted by the Government or the Awardee (collectively, the "Study Data"), shall be owned by the Awardee. The U.S. Government shall have the right to use, modify, reproduce, release, perform, display, or disclose data first produced in the performance of this Agreement within the Government and otherwise including use for Government procurement of the items covered by the data, provided however, that any "protected health information" (as defined in the HIPAA Privacy Rule) may only be used to the extent consistent with the informed consent and/or authorization documents signed by research subjects participating in the underlying clinical research studies. The Government may, under a separate agreement or by modification to this agreement through good faith negotiations and only as consistent with applicable law, obtain any rights to use or disclose the Awardee's material or data to the extent that such material or data was produced outside the scope of this Agreement. This Agreement involves human subject research data conducted under the federal and state regulations. Nothing herein shall authorize the Government to use or further disclose the Study Data in a manner that would violate applicable state and federal regulations related to the conduct of human subject research, including but not limited to 45 CFR Part 46, and 45 CFR 164.514. Provider shall only provide analyzed Study Data, or identified Study Data (as defined under applicable law). The Government shall not make any effort to identify or contact individuals who are or may be the sources of Data without specific written approval from Provider and appropriate Institutional Review Board approval, if required pursuant to 45 CFR Part 46. Should Government inadvertently receive identifiable information or otherwise identify a subject, Government shall promptly notify Provider and follow Provider's reasonable written instructions, which may include return or destruction of the identifiable information.

Notwithstanding the above, as a result of this Agreement, the Government shall obtain "Unlimited rights," as this term is defined in DFARS 252.227-7013(a)(16) in any data generated under this agreement, provided

however, that any “protected health information” (as defined in the HIPAA Privacy Rule) may only be used to the extent consistent with the informed consent and/or authorization documents signed by research subjects participating in the underlying clinical research studies.

B. The Awardee agrees to retain and maintain in good condition until five (5) years after completion or termination of this Agreement, all data generated under this Agreement. In the event of exercise of the Government's rights as potentially granted under Article 2.C, the Awardee agrees to deliver at no additional cost to the Government except the cost of converting the data or computer software into the prescribed form, for reproduction and delivery, all data, in Awardee's possession and developed under this Agreement, necessary to develop the Prototype within sixty (60) calendar days from the date of the written request.

C. Marking of Data: The Awardee will mark any data delivered under this Agreement with the following legend at a minimum:

"Use, duplication, or disclosure is subject to the restrictions as stated in Agreement (b) (4) between the Government and the Awardee."

Any rights that the Awardee or the Government may have in data delivered under this Agreement, whether arising under this Agreement or otherwise, will not be affected by Awardee's failure to mark data pursuant to this Article.

Any distribution markings shall be established by the GPM and incorporated prior to distribution.

D. All Software (as that term is defined in DFARS 252.227-7014) developed under this agreement shall be owned by the Awardee subject to “Unlimited Rights” (as that term is defined in DFARS 252.227-7014) held by the Government. The Awardee shall deliver source and object code for each instance of Software developed under the agreement in accordance with the requirements of the other deliverables under this Agreement. Use of any open source code in any Software required to be delivered to the Government shall be subject to approval of the Government.

E. All Technical Data and Software (each term as defined under DFARS 252.227-7013) which shall be delivered under this agreement with less than unlimited rights shall be identified in reasonable specificity and particular rights granted (Government Purpose, Limited or Restricted (all as defined in DFARS 252.227-7013)) prior to entering into the agreement. All other Technical Data and Software developed under funding of this agreement shall be delivered with unlimited rights as provided for within this Article.

## **ARTICLE 12 Regulatory Rights.**

This Agreement includes research with an investigational drug, biologic or medical device that is regulated by the U.S. Food and Drug Administration (FDA) and requires FDA pre-market approval or clearance before commercial marketing may begin. It is expected that this Agreement may result in the FDA clearance and commercialization of convalescent COVID-19 Human Coronavirus Immune Plasma (HCIP). The Awardee's employee Dr (b) (6) is the Sponsor of the Regulatory Application (an investigational new drug application (IND), investigational device exemption (IDE), new drug application (NDA), biologics license application (BLA), or another regulatory filing submitted to FDA) that controls research under this Agreement. As the Sponsor of the Regulatory Application to FDA (as the terms “sponsor” and “applicant” are defined or used in at 21 CFR §§3.2(c), 312.5, 600.3(t), 812.2(b), 812 Subpart C, or 814.20), the Awardee has certain standing before

the FDA that entitles it to exclusive communications related to the Regulatory Application. This clause protects the return on research and development investment made by the Government in the event of certain regulatory product development failures related to the Technology.

Good Clinical Practices (GCP) Compliance. Awardee and Awardee’s Principal Investigators shall carry out the Study in compliance with generally accepted standards of Good Clinical Practice promulgated by the International Conference on Harmonization (“ICH-GCPs”), but only to the extent such ICH-GCPs have been accepted by the United States Food and Drug Administration (“FDA”), as set forth in Title 21 of the U.S. Code of Federal Regulations (“C.F.R.”).

The Awardee agrees to the following:

A. Communications. Awardee will provide Government with copies of all IRB-approved study protocols, consent forms and authorization documents, as well as documentation of approvals for such protocols by the FDA, the Awardee’s IRB, and any other applicable regulatory bodies. Upon becoming aware of an audit or investigation by the FDA or other regulatory agency with jurisdiction over a study performed hereunder, Awardee agrees to provide Government with prompt notice of the audit or investigation, and will provide Government with a copy of any formal response or documentation to the regulatory agency.

B. The Senior Director Medical Regulatory (SDMR), who is the JPEO-CBRND and DTRA-JSTO representative for all regulatory activities with the FDA. The Awardee shall advise the SDMR prior to meeting with the FDA.

C. Rights of Reference. The Government is hereby granted a right of reference to any regulatory application submitted in support of the statement of work of this Agreement. Awardee agrees to provide a letter of cross-reference to the Government and file such letter with the appropriate FDA office. Nothing in this paragraph reduces the government’s data rights as articulated in other provisions of this award.

D. PL-115-92 allows the DoD to request, and FDA to provide, assistance to expedite development and the FDA’s review of products to diagnose, treat, or prevent serious or life-threatening diseases or conditions facing American military personnel. The Awardee recognizes that only the DoD can utilize PL 115-92. As such, the Awardee will work proactively with the SDMR to leverage this this law to its maximal potential under this OTA (alternate language: for this prototype). The Awardee shall submit Public Law 115-92 Sponsor Authorization Letter that will be delivered to JPM CBRN Medical within 30 days of award.

**ARTICLE 13. Foreign Access to Data.**

Export Compliance: The Parties will comply with any applicable U.S. export control statutes or regulations in performing this Agreement.



## **ARTICLE 14. Scientific Publications and Press Releases.**

A. The Parties shall jointly agree on a communication plan for the data derived from studies executed under this Agreement (such data to be considered New Data). This plan will identify key New Data to be disclosed or presented and the target date for finalizing any related scientific abstract or manuscript. As part of its Quarterly Program Reviews, the Awardee will share the publication plan with the Government.

B. The Parties may separately develop an abstract or manuscript and authorship and the content of the final draft to be submitted; provided that authorship for each abstract and manuscript will be determined based on whether a particular individual made a significant contribution to the conceptualization, design, execution, or interpretation of a research study, as authorship is defined in the fifth edition of the Guidelines and Policies for the Conduct of Research in the Intramural Research Program at NIH, available at: [https://oir.nih.gov/sites/default/files/uploads/sourcebook/documents/ethical\\_conduct/guidelines-conduct\\_research.pdf](https://oir.nih.gov/sites/default/files/uploads/sourcebook/documents/ethical_conduct/guidelines-conduct_research.pdf).

C. Prior to submission for publication, the Parties shall provide drafts of proposed publications to the authors of such publications for review and comment, and shall provide copies to non-authors for viewing purposes. Review periods are ten (10) business days for abstracts, or less than ten (10) business days if agreed by Project Managers and in order to meet publication submission deadlines. Review periods are twenty (20) calendar days for manuscripts. Contributing parties shall be appropriately accredited in any publication.

D. The Parties will collaborate on whether to issue one or more press releases related to the resulting New Data. If a Party seeks to issue a press release, each Party will also have the right to review and agree on the content in advance of its press release. Other parties, if any, contributing to the studies, will have review rights and will be appropriately accredited in the press release. For data generated in studies executed by Awardee outside the scope of this Agreement, the Awardee, at its sole discretion, may issue a press release related to such data.

E. In order to preserve Awardee's publication rights with respect to clinical trials pursuant to the registration requirements, the studies hereunder will be registered on [www.clinicaltrials.gov](http://www.clinicaltrials.gov) in accordance with the requirements of the International Committee of Medical Journal Editors (ICMJE) and Public Law 110-85. Results of this Study will be reported in compliance with applicable laws.

## **ARTICLE 15. Miscellaneous Clauses.**

A. Limitation of Liability. Except as otherwise provided in this agreement, neither Party shall be liable to the other Party or any third party claiming through such Party for any indirect, incidental, consequential or punitive damages, or claims for lost profits, arising under or relating to this Agreement, whether based in contract, tort or otherwise, even if the other Party has been advised of the possibility of such damages. Notwithstanding the above, the parties intend that the studies performed hereunder will be subject to the terms of the March 10, 2020 declaration under the Public Readiness and Emergency Preparedness Act (PREP Act), 42 U.S.C. § 247d-6d, 85 Fed Reg. 15,198 (March 17, 2020), PREP Act which provides for certain liability protections and immunity from suit and liability under U.S. federal and state law with respect to claims involving use of a covered countermeasure during an epidemic. In accordance with the Declaration by the U.S. Secretary of Health and Human Services effective February 4, 2020 that the spread of SARS-CoV-2 constitutes a public health emergency, pursuant to the PREP Act Declaration issued by DHHS on March 10, 2020, pursuant to section 319F-3 of the Public Health Service Act (42 U.S.C. 247d-6d), and a related advisory opinion issued by the DHHS Office of General Counsel on April 14, 2020, the Parties that

the studies hereunder are being conducted in response to a public health emergency and in accordance with the response of international governments and health authorities, and the parties intend that interventions under these studies constitutes a Covered Countermeasure as defined in the PREP Act.

B. Disclosure of Information. Subject to Articles 10 and 11, the Awardee shall not release to anyone outside the Awardee's organization any unclassified information deemed Confidential Information and marked or identified as such, regardless of medium (e.g., film, tape, document), pertaining to any part of this Agreement or any program related to this Agreement, unless (i) the Agreements Officer has given prior written approval or (ii) the information is otherwise in the public domain before the date of release.

C. Force Majeure. Neither Party will be liable to the other Party for failure or delay in performing its obligations hereunder if such failure or delay arises from circumstances beyond the control and without the fault or negligence of the Party (a Force Majeure event). Examples of such circumstances are: authorized acts of the government in either its sovereign or contractual capacity, war, insurrection, freight embargos, fire, flood, or strikes. The Party asserting Force Majeure as an excuse must take reasonable steps to minimize delay or damages caused by unforeseeable events.

D. Severability. If any provision of this Agreement, or the application of any such provision to any person or set of circumstances, is determined to be invalid, unlawful, void or unenforceable to any extent, the remainder of this Agreement, and the application of such provision to persons or circumstances other than those as to which it is determined to be invalid, unlawful, void or unenforceable, will not be impaired or otherwise affected and will continue to be valid and enforceable to the fullest extent permitted by law.

E. 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 either directly or indirectly or by operation of law. When a specific FAR 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.

F. Order of Precedence. In the event of a conflict between the terms of this Agreement and the attachments incorporated herein, the conflict shall be resolved by giving precedence in descending order as follows: (i) the Articles of this Agreement, and (ii) the Appendices to the Agreement.

G. Insurance -- Liability to Third Persons. The Awardee shall be reimbursed for certain liabilities, and expenses incidental to such liabilities, to third persons not compensated by insurance or otherwise without regard to and as an exception to the limitation of Government Liability otherwise contained in this agreement that arise out of the performance, whether or not caused by the negligence of the Awardee or of the Awardee's agents, servants, or employees, and must be represented by final judgments or settlements approved in writing by the Government for loss of or damage to property, or death or bodily injury. The Government's liability under this clause is subject to the availability of agreement funds at the time a contingency occurs. Nothing in this agreement shall be construed as implying that the Congress will, at a later date, appropriate funds sufficient to meet deficiencies.

## Appendix A

### Statement of Work

The Awardee plans to execute the program in accordance with the statement of work provided below. The plan is to accomplish the entire project based on the schedule prescribed in this agreement. Completion dates are expressed in Appendix B. The numbering scheme below is adopted from the Awardee's Statement of Work as included in its proposal. Only the sections of the proposal included in this Appendix A are made a part of this Agreement. Unless otherwise indicated below, all tasks will be carried out at the Awardee's facilities.

#### A. Statement of Work (SOW)

##### Project Description

This project involves conducting (b) (4) randomized, (b) (4) controlled clinical trials (RCT's), (b) (4) [REDACTED] that evaluate the feasibility, safety and efficacy of convalescent plasma in the control of COVID-19. These are Investigator-Initiated Trials (IIT's) conducted under an Investigational New Drug (IND) exemption from the US Food and Drug Administration (FDA). The applicable IND is # 19725 and (b) (6) [REDACTED], MD is the Sponsor-Investigator.

Study-001 will enroll (b) (4) [REDACTED] patients at high-risk of infection with the treatment-failure endpoint being confirmed diagnosis of COVID-19. Study-004 will enroll (b) (4) [REDACTED] confirmed-positive patients with the treatment-failure endpoint being hospitalization. Each study will follow enrolled subjects (b) (4) [REDACTED], with treatment-success for a patient being assigned after reaching a (b) (4) [REDACTED] day endpoint. The (b) (4) [REDACTED] follow-up is mainly for immunologic final outcome. Safety will be determined based on a review of adverse events between the treated and untreated groups, with randomization at a 1:1 treatment allocation. (b) (6) [REDACTED] and (b) (6) [REDACTED] are the Principal Investigators of Study-001 and Study-004 RCT's respectively (the "Principal Investigators").

(b) (4) [REDACTED] US-based clinical sites will be activated, most of which will participate in both studies. Plasma will be collected from volunteers who have recovered from COVID-19 and processed either on-site or at a central facility for administration to study participants. A second goal of this project is to develop a functional network, using these clinical sites or a subset thereof, to support the ongoing procurement and biobanking of plasma from convalescent COVID-19 patients with high antibody titers to generate a national stockpile (b) (4) [REDACTED]. Dr. (b) (6) [REDACTED] is the Principal Investigator of the non-randomized, noninterventional donor qualification protocol that will be used at participating clinical sites in connection with the collection of convalescent plasma.

##### Project Charter

These (b) (4) [REDACTED] studies were initiated by academic researchers in early 2020, to include study design, protocol development, IND submission, and study setup. As of mid-May 2020, fifteen

(b) (4) have been pre-qualified and should be ready for activation shortly after grant award. The project team is submitting this request (b) (4) to fund the implementation of these parallel studies to include site setup, enrollment, and data collection, analysis & reporting activities.

### **Project Objective**

The objective of this project is to conduct (b) (4) RCTs that meet all specific aims and requirements as defined in the respective clinical protocols. At the conclusion of the project, the ultimate objective is to publish the study results (and make the clinical database publicly available) both as a study report for FDA and DOD review, and subsequently in an accredited medical journal as a means of broadly disseminating the study findings to clinicians treating this medical condition. It is the hope of the project team and stakeholders that convalescent plasma will prove to be a safe and effective treatment for COVID-19 addressing an urgent and critical need during a pandemic.

### **Project Constraints**

The primary constraints on this project are the following:

- Amount of funding, which limits the number of sites as well as the size of the project team, both of which impact the duration of the trial;
- Time to receipt of funding, which impacts when the project may be launched;
- Applicable regulations and Good Clinical Practice standards, which require certain procedures and establish certain legally enforceable obligations related to trial conduct and reporting.
- Broad infection controls implemented by national and local authorities as result of the current COVID-19 pandemic, which may present certain hurdles to study conduct; and
- The need to complete the trial rapidly due to the urgent national need for COVID-19 therapies.

### **Assumptions**

This plan entails the following assumptions:

- Grant award by 30-May 2020 and expeditious release of funds to support project launch by in June 2020 (a later start date will shift the timeline forward);
- Availability of all required supplies and materials, to include personal protective equipment, testing supplies, and other medical supplies (i.e., ability to overcome national shortages, limited availability of testing); and
- The potential patient population (newly diagnosed COVID-19 patients) remains adequate to meet the enrollment goals with no unexpected change in extent of or access to this population (i.e., such as early development and distribution of a vaccine or prophylactic).

### **General Requirements**

DOD, specifically the JPEO-CBD, is funding this project; the project will therefore need to be conducted in accordance with the DOD's requirements. This usage of convalescent plasma in the treatment of COVID-19 is experimental and regulated under the FDA's IND (21 CFR 312 et. seq.) regulations; FDA has awarded the IND for this project. Other FDA clinical research

regulations are applicable to this project, including 21 CFR Parts 50 (Informed Consent) and 56 (IRBs). As well, the project will be conducted in general accordance with the ICH E6(R2) Good Clinical Practice guidance, published by FDA in March 2018. FDA guidance documents are non-binding recommendations, allowing trial sponsors to use alternative approaches provided they comply with applicable regulations.

As the U.S. sites are covered entities under the U.S. Health Insurance Portability and Accountability Act (HIPAA), the study shall be conducted in compliance with the HIPAA Privacy Rules as well. This will require ensuring that patients execute HIPAA waivers before collecting any protected health information (PHI) as well as controlling access to the data collection system and ensuring that all patient identifiers (including site names and procedure dates) are removed prior to any dissemination of the clinical data or study results.

Other regulations apply such as FDA's regulations regarding collection of Electronic Records and Electronic Signatures (21 CFR 11). This entails, among other requirements, using properly validated data management systems and maintaining data security and integrity controls.

All of these requirements are well-established best practice in regulated clinical trials and incorporated into the project team's policies and Standard Operating Procedures (SOPs).

## APPLICABLE DOCUMENTS

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### **Study Documents**

- Convalescent Plasma Protocol 001
- Convalescent Plasma Protocol 004

### **FDA Documents**

- FDA Regulations: Investigational New Drug (IND) Application (21 CFR Part 312)
- FDA Regulations: Electronic Records – Electronic Signatures (21 CFR Part 11)
- FDA Regulations: Protection of Human Subjects (21 CFR Part 50)
- FDA Regulations: Financial Disclosure by Clinical Investigators (21 CFR Part 54)
- FDA Regulations: Institutional Review Boards (21 CFR Part 56)
- FDA Regulations: Requirements for Blood and Blood Components Intended for Transfusion or for Further Manufacturing Use (21 CFR Part 630)
- FDA Regulations: Additional Standards for Human Blood and Blood Products (21 CFR Part 640)
- FDA Guidance: ICH E6(R2) Good Clinical Practice: Integrated Addendum, March 2018
- FDA Guidance: ICH E3 Structure and Content of Clinical Study Reports, July 1996
- FDA Guidance: Investigational COVID-19 Convalescent Plasma, May 2020

### **Other Documents**

- International Air Transport Association (IATA): Dangerous Goods Regulations (DGR)
- Society of Clinical Data Management (SCDM): Good Clinical Data Management

## REQUIREMENTS

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### Deliverables and Specifications

The key deliverables and associated specifications for this project are as follows.

#### 1. Development and operationalization of a plasma procurement process.

- 1.1. At least (b) (4) of sites will establish a collection and processing capability at their respective organizations.
- 1.2. Each participating site will collect, process and bank (b) (4) units.
- 1.3. Sites shall have evidence of CLIA certification.
- 1.4. At least one member at each site shall have evidence of training on IATA's DGM (shipping of dangerous material) regulations.
- 1.5. Donor eligibility shall be determined in compliance with an IRB-approved protocol and FDA's 21 CFR regulations Part 630.10 (General Eligibility Requirements) and Part 630.15 (Requirements specific to plasma collected by apheresis) under appropriate medical supervision per Part 630.5 (Medical Supervision).
- 1.6. Blood processing will be performed in compliance with an IRB-approved protocol and FDA's 21 CFR Part 640.64 (Collection of Blood for Source Plasma).
- 1.7. Post-processing, plasma shall be handled as an investigational product under the applicable IND regulations (21 CFR 312 et. Seq.) and in general accord with the E6(2) Good Clinical Practice guidance, including §5.14 (Supplying and Handling Investigational Product).

#### 2. Qualification and activation (b) (4) sites.

- 2.1. Experienced site investigators shall be selected from the NIH/NCATS Clinical & Translational Science Awards (CTSA) consortium and qualified by the Trial Innovation Network (TrialInnovationNetwork.org) in compliance with FDA regulations 21 CFR 312.50 (General Responsibilities of Sponsors) and 312.53 (Selecting Investigators) and in general accordance with E6(R2) §4.1 guidance (Investigator Qualifications and Agreements).
- 2.2. All participating investigators shall sign the FDA Statement of Investigator (Form 1572) committing the investigator to conduct the trial in accordance with the protocol, to personally supervise the investigation and to report adverse experiences, as well as agree to comply with E6(R2) guidance including §4.5 (Compliance with Protocol).
- 2.3. Clinical sites shall be verified to have adequate resources as per E6(R2) §4.2.
- 2.4. Prior to activation, clinical sites shall have received approval from a single/central IRB that complies with 21 CFR 56, as required under 21 CFR 312.66 and according to the guidance under E6(R2) §4.4 (Communication with IRB/IEC).
- 2.5. Investigator compliance and data quality shall be monitored by the sponsoring project team in accordance with 21 CFR 312.56 (Review of Ongoing Investigations) by qualified monitors.
- 2.6. The studies shall have a risk-based system to manage quality throughout all stages of the

trial process that follows the guidance under E6(R2) §5.0 (Quality Management).

**3. Enrollment of COVID-19 patients and collection of associated clinical data for evaluating the study aims per the study protocols.**

- 3.1. Prior to enrollment, participants will have provided informed consent per 21 CFR 50 as approved by an IRB conforming with 21 CFR 56 requirements.
- 3.2. Suitable QA/QC procedures shall be implemented with written Standard Operating Procedures (SOPs) governing trial conduct, data collection and data reporting following the guidance under E6(R2) §5.1 (Quality Assurance and Quality Control)
- 3.3. Project team compliance with the protocol and SOPs will be periodically audited per SOPs and a written risk-based quality plan in general accordance with E6(R2) §5.19 (Audit) and §5.20 (Noncompliance)
- 3.4. Study documentation will be maintained in compliance with 21 CFR 312.57 and in general accordance with the guidance in E6(2) §8.0 (Essential Documents for the Conduct of a Clinical Trial).
- 3.5. Enrollment and data collection will be conducted in accordance with the protocol and all applicable regulations (i.e., 21 CFR 11, 50, 56, 312, HIPAA) and in general accordance with the E6(R2) guidance (Good Clinical Practice).
- 3.6. Any delegation to a sub-contracted vendor (other than clinical sites) will comply with 21 CFR 312.52 and in general accord with E6(2) §5.2 (Contract Research Organizations).
- 3.7. Patient safety will be monitored by qualified medical personnel in general accordance with the E6(R2) §5.3 guidance.
- 3.8. Participant safety will be reviewed periodically by an appropriately organized Data Safety Monitoring Board (DSMB) having the authority to stop the trial should the risk exceed the expected benefit.
- 3.9. The clinical investigators, FDA, the IRB and the DSMB will be kept informed of safety information in compliance with 21 CFR 312.55 (Informing Investigators) and in general accordance with the guidance in E6(R2) §5.16.

**4. A finalized study report regarding the database that allows a statistically valid and adequately powered assessment of the protocol-defined aims.**

- 4.1. Clinical data will be monitored for quality and data integrity, and the clinical sites will be monitored for protocol and regulatory compliance, by monitors qualified per 21 CFR 312.53(d) operating under the E6(R2) guidance in §5.18 (Monitoring) and in accordance with a written monitoring plan that complies with the project's written risk-based quality management plan and the FDA's August 2013 guidance on A Risk-Based Approach to Monitoring.
- 4.2. Data management and statistical analysis will be conducted by qualified staff, operating under appropriate SOPs, in general accordance with the Good Clinical Data Management Practices guidance from the Society of Clinical Data Management (SCDM) and all applicable regulations.

**5. An Integrated Final Clinical & Statistical Study Report ("final report") for submission to FDA, DOD and other stakeholders.**

- 5.1. The clinical report will be developed in general accordance with FDA’s E3 (Structure and Content of Clinical Study Reports) guidance.
- 5.2. A discussion of study results shall be submitted for publication in an accredited medical journal.
- 5.3. Suitable data listings will be submitted to clinicalTrials.gov.

**B. Work Breakdown Structure**

The following represents a high-level Work Breakdown Structure (WBS) for this project, mapped to the resources (roles) listed in the budget and the deliverables listed above.

**1. Plasma Procurement Core**

Resources: (b) (4)

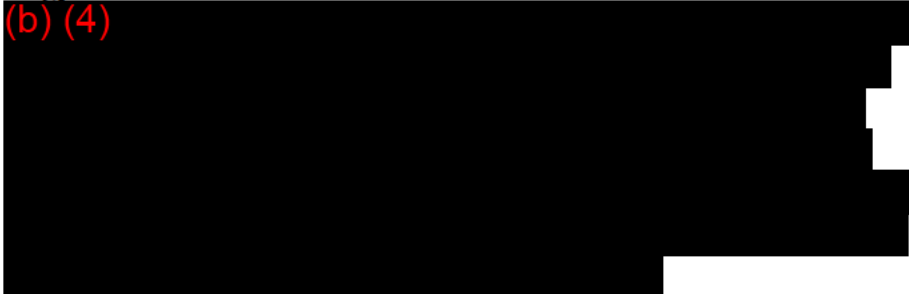


Activities: (b) (4)



**2. Virology and Immunology Core**

Resources: (b) (4)



Activities: (b) (4)





(b) (4)

### 3. Clinical Coordinating Center Core

Resources: Regulatory Coordinator, IRB Navigator, Site Navigator, Site Manager, Project Manager, Project Director, Departmental Administrator, Departmental Director, Senior Director, sIRB (fixed cost)

Activities: #2 (Site Qualification & Activation), #3 (Enrollment & Data Collection)

3.1. Single IRB (sIRB)

3.2. Clinical Site Selection and Qualification (“Site Startup”)

3.3. Site Management & Study Conduct

### 4. Data Coordinating Center Core

Resources: Data Manager, Monitor (vendor), Biostatistician, Medical Writer, Project Manager, Project Director, Director of Quality Assurance (vendor), Departmental Administrator, Departmental Director, Senior Director, DSMB (external), EDC System (vendor)

Activities: #4 (Finalized Database), #5 (Final Report)

4.1. DSMB

4.2. Clinical Data Repository Setup

4.3. Monitoring & Quality Assurance

## Project Timeline

As of 21-May, the New York Times is reporting approximately 20,000 new cases of COVID-19 per day. Although the infection rate has declined from a peak of around 36,725 cases on 24-April, the rate recently appears to be leveling off. With the relaxing of at-home orders across the country, it could be reasonably assumed that this average daily incidence of new cases is unlikely to drop precipitously over the next few months. Consequently, recruitment in these studies should not be difficult. Further, it is expected that US citizens will be very willing to donate plasma for this study.

The following enrollment projection is based on the following metrics, which are reflected in the graph of projected enrollment below and the associated project timeline (b) (4) Chart).

(b) (4)

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

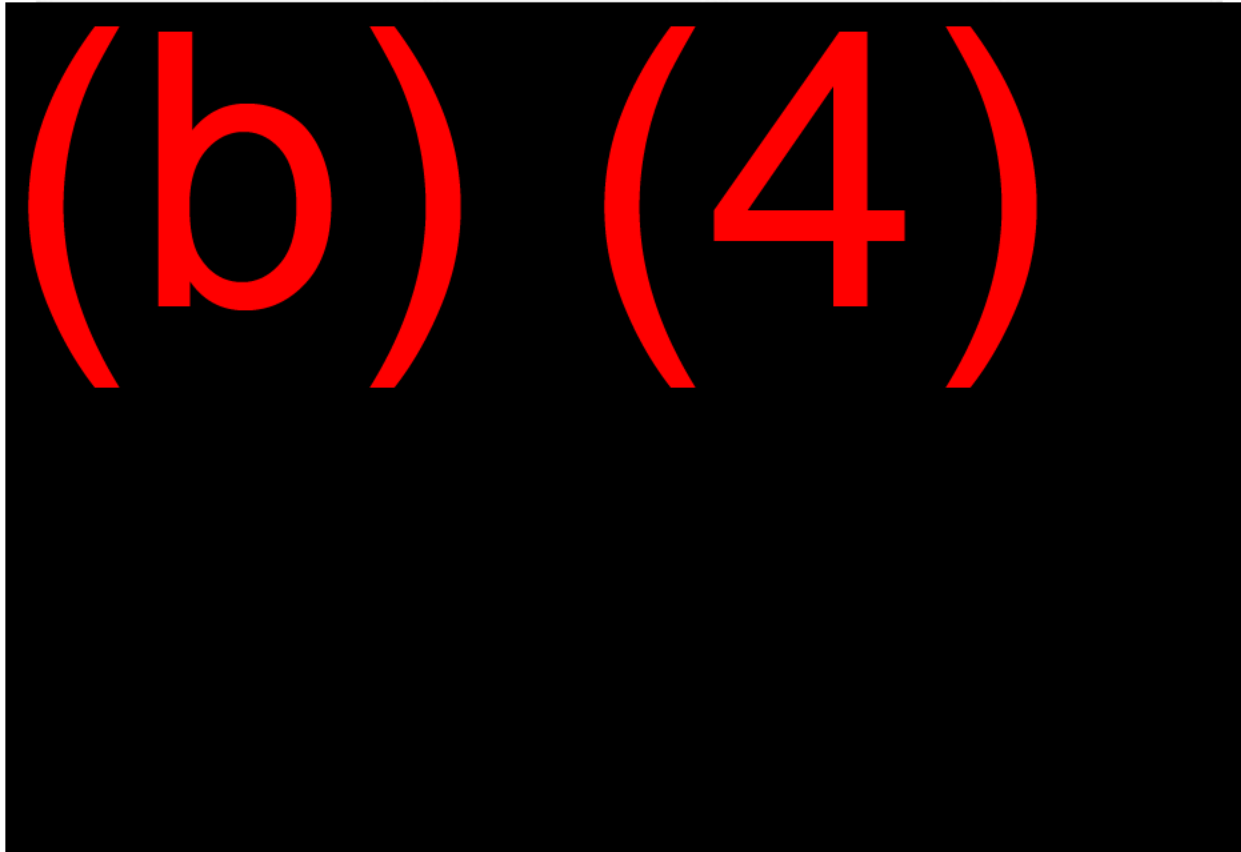
[REDACTED]

[REDACTED]

(b) (4)

(b) (4)

The table below lists the periods from the above (b) (4) chart, the milestones that signify the start and end of each period, and the duration of each period in calendar days.



The project lifecycle is represented in the sequence diagram below, where the abbreviations (green circles) represent major milestones and the arrows represent periods from the above (b) (4) chart, with the period durations appearing as small numbers above the arrows.



This final table expands upon the WBS and enrollment projection to establish milestones for critical study events. The planned dates and elapsed project day are shown in the last two columns. The Code column shows the abbreviations used in the lifecycle diagram above.

(b) (4)

The milestones listed in this table are generated from the timeline calculations and combines the two studies. It should be noted that this projection is based on certain assumptions (such as the grant being awarded in time to allow project launch on 01-June 2020) and disregards non- workdays. Notably, it also does not incorporate any contingency lags and assumes best-case scenarios. As such, for project performance purposes, the dates should be given a window of +/- two weeks.

This table lists the tasks completed to-date in preparation for the launch of this project.

(b) (4)	(b) (4)	(b) (4)	(b) (4)
(b) (4)	(b) (4)	(b) (4)	(b) (4)
(b) (4)	(b) (4)	(b) (4)	(b) (4)

(b) (4)	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

## Appendix B

### Project Schedule/ Payment Schedule

#### 1. Payment Schedule

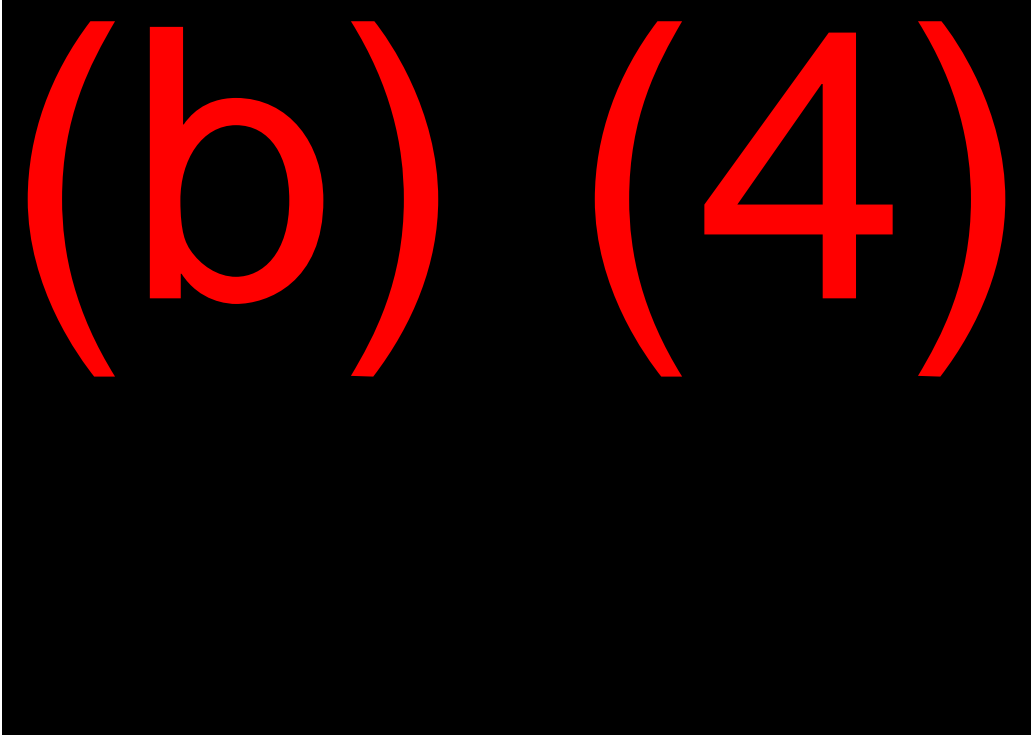
The Government shall pay the Awardee, upon the submission of proper invoices or vouchers, the prices stipulated in this Agreement for all direct and indirect costs under this Agreement, plus a pro rata of fee if applicable, on a cost-reimbursable basis. Expenditures shall be submitted based on the awarded budget. Federal funds are to be used only for costs that a reasonable and prudent person would incur in carrying out the prototype project. The Awardee must maintain a financial system capable of identifying costs applicable to this Agreement, compliant with Cost Principles (48 CFR Part 31) and/or the Cost Accounting Standards (CAS) (48 CFR Part 99). An invoice will be submitted monthly through Wide Area Work Flow (WAWF) in accordance with agreement requirements. Final payment of the Agreement shall be determined upon mutual agreement and settlement of any outstanding costs.

The Awardee shall proceed with the performance in accordance with the terms and conditions of this Agreement and its Appendices. However, the Government may require the Awardee to cease performance at any time prior to the commencement of any milestone or task. Such notice to cease performance must be from the OTA0 and be in writing, of which email is an acceptable form.

Subaward agreements with the (b) (4) identified in the proposal will require OTA0 review and approval prior to execution.

**2. Project Schedule**

The following project timeline is hereby incorporated into the agreement as the target project timeline. Any adjustments to this timeline shall be negotiated and updated by the OTAO accordingly.



## **Appendix C Personnel**

### **1. Awardee's Organization and Key Personnel.**

- a. The Contactor's organization shall be established with authority to effectively accomplish the objectives of the Statement of Work. This organization shall become effective upon award of the Agreement and its integrity shall be maintained for the duration of the agreement effort
  
- b. The key personnel listed below are considered to be critical to the successful performance of this Agreement. Prior to replacing these key personnel, the Awardee shall obtain the written consent of the Agreements Officer. In order to obtain such consent, the Awardee shall provide advance notice of the proposed changes and shall demonstrate that the qualifications of the proposed substitute personnel are generally equivalent to or better than the qualifications of the personnel being replaced.
  
- c. Prior to permanently removing any of the specified individuals to other contracts, the Awardee shall provide the Agreements Officer not less than thirty (30) calendar days advance notice and shall submit justification (including proposed substitutions) in sufficient detail to permit evaluation of the impact on the program. The "Key Personnel" list may be amended from time to time during the course of the Agreement to either add or delete personnel, as appropriate.

Key Personnel:

(b) (6) Principal Investigators of Study-001 and Study-004 RCT's respectively.

(b) (6)

Each of these individuals bear regulatory responsibilities in connection with their roles in those respective research studies



## **Appendix D Government Property**

Government Property: “Government Property” means any property (i) furnished by the Government and facilitating performance of this Agreement, (ii) acquired by the Awardee under cost reimbursement terms of this Agreement, or (iii) acquired by the Awardee at the Government’s cost under fixed price terms of this Agreement (FP-GP) and specifically identified in this Government Property Appendix. Except for commercial off the shelf software and licenses thereto, Government Property does not include intellectual property and software. The Government owns and holds title to all Government Property.

The Government shall deliver to the Awardee any Government Property required to be furnished as described in this Agreement together with related data and information needed for its intended use. The delivery and/or performance dates specified in this Agreement are based upon the expectation that the Government-furnished property will be suitable for performance and will be delivered to the Awardee by the dates stated in the Agreement. If not so suitable, the Awardee shall give timely written request to the OTA0 who will advise the Awardee on a course of action to remedy the problem.

FPGP includes: None

The Awardee shall have, initiate and maintain a system of internal controls to manage, control, use, preserve, protect, repair, account for and maintain Government Property in its possession and shall initiate and maintain the processes, systems, procedures, records required control and maintain accountability of Government Property. The Awardee shall include this clause in all subcontracts under which Government Property comes into the possession of any subAwardee. Unless otherwise provided for in this Agreement or approved by the OTA0, the Awardee shall not: (i) use Government Property for any purpose other than to fulfill the requirements of this Agreement, or (ii) alter the Government Property.

The Awardee shall establish and implement property management plans, systems, and procedures regarding its acquisition of Government Property, its receipt of Government Property, in addition to, the status, dates furnished or acquired, identification, quantity, cost, marking, date placed in service, location, inventory and disposition of Government Property, to include a reporting process for all discrepancies, loss of Government Property, physical inventory results, audits and self-assessments, corrective actions, and other property related reports as directed by the OTA0.

Upon conclusion or termination of the Agreement, the Awardee shall submit a request in writing to the OTA0, for disposition/disposal instructions and shall store Government Property not to exceed 120 days pending receipt of such instructions. Storage shall be at no additional cost to the Government unless otherwise noted in the Agreement. The Government, upon written notice to the Awardee, may abandon any Government Property in place, at which time all obligations of the Government regarding such Government Property shall cease.

**Awardee Liability for Government Property.** “Loss of Government Property” means the loss, damage or destruction to Government Property reducing the Government’s expected economic benefits of the property and includes loss of accountability but does not include planned and purposeful destructive testing, obsolescence, normal wear and tear or manufacturing defects. THE AWARDEE SHALL ONLY BE LIABLE FOR LOSS OF GOVERNMENT PROPERTY WHEN (1) THE RISK IS COVERED BY INSURANCE OR OTHERWISE REIMBURSED, OR (2) THE LOSS IS THE RESULT OF WILLFUL MISCONDUCT OR LACK OF GOOD FAITH ON THE PART OF THE AWARDEE’S MANAGERIAL PERSONNEL. The Awardee shall take all reasonable actions necessary to protect the property from further loss, and shall do nothing to prejudice the Government's rights to recover against third parties for any loss of Government property.

<b>AWARD/CONTRACT</b>		1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)			RATING	PAGE OF PAGES 1   12	
2. CONTRACT (Proc. Inst. Ident.) NO. W911QY2090012F00005		3. EFFECTIVE DATE 08 Jun 2020			4. REQUISITION/PURCHASE REQUEST/PROJECT NO. SEE SCHEDULE		
5. ISSUED BY W6QK ACC-APG NATICK CONTRACT NG DIVISION BLDG 1 GENERAL GREENE AVENUE NATICK MA 01760-5011		CODE W911QY	6. ADMINISTERED BY (If other than Item 5) W6QK ACC-APG NATICK 110 THOMAS JOHNSON DR SUITE #240 FREDERICK MD 21702			CODE W911QY	
7. NAME AND ADDRESS OF CONTRACTOR (No., street, city, county, state and zip code) JOHNS HOPKINS UNIVERSITY, THE 3400 N CHARLES ST BALT MORE MD 21218-2608				8. DELIVERY <input type="checkbox"/> FOB ORIGIN <input checked="" type="checkbox"/> OTHER (See below)		9. DISCOUNT FOR PROMPT PAYMENT	
CODE 5L406		FACILITY CODE			10. SUBMIT INVOICES (4 copies unless otherwise specified) TO THE ADDRESS SHOWN IN:		ITEM
11. SHIP TO/MARK FOR  <b>See Schedule</b>		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 HQ490	
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 <b>See Schedule</b>			
15A. ITEM NO.	15B. SUPPLIES/ SERVICES		15C. QUANTITY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT	
<b>SEE SCHEDULE</b>							
<b>15G. TOTAL AMOUNT OF CONTRACT (b) (4)</b>							
<b>16. TABLE OF CONTENTS</b>							
(X)	SEC.	DESCRIPTION	PAGE(S)	(X)	SEC.	DESCRIPTION	PAGE(S)
<b>PART I - THE SCHEDULE</b>				<b>PART II - CONTRACT CLAUSES</b>			
X	A	SOLICITATION/ CONTRACT FORM	1 - 4	I	CONTRACT CLAUSES		
X	B	SUPPLIES OR SERVICES AND PRICES/ COSTS	5 - 6	<b>PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACH.</b>			
	C	DESCRIPTION/ SPECS/ WORK STATEMENT		J	LIST OF ATTACHMENT S		
	D	PACKAGING AND MARKING		<b>PART IV - REPRESENTATIONS AND INSTRUCTIONS</b>			
X	E	INSPECTION AND ACCEPTANCE	7	K	REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS		
X	F	DELIVERIES OR PERFORMANCE	8		OTHER STATEMENTS OF OFFERORS		
X	G	CONTRACT ADMINISTRATION DATA	9	L	INSTRS., CONDS., AND NOTICES TO OFFERORS		
	H	SPECIAL CONTRACT REQUIREMENTS		M	EVALUATION FACTORS FOR AWARD		
<b>CONTRACTING OFFICER WILL COMPLETE ITEM 17 (SEALED-BID OR NEGOTIATED PROCUREMENT) OR 18 (SEALED-BID PROCUREMENT) AS APPLICABLE</b>							
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) / CONTRACT SPECIALIST TEL: (b) (6) EMAIL: (b) (6)			
19B. NAME OF CONTRACTOR		19C. DATE SIGNED		20B. UNITED STATES OF AMERICA <b>(b) (6)</b>		20C. DATE SIGNED 08-Jun-2020	
BY _____ (Signature of person authorized to sign)				BY _____ (Signature of Contracting Officer)			

Section SF 30 - BLOCK 14 CONTINUATION PAGE

P00001

A. The purpose of this modification is to incorporate additional effort as follows:

1. The total cost of CLIN 0001 is increased from (b) (4), by (b) (4), to \$35,050,323.00.
2. SubCLIN 000102 is hereby added to incorporate additional funding in the amount of (b) (4).
3. Appendix A of the Agreement is hereby revised to incorporate the additional effort identified in the Awardee's proposal dated 19 June 2020.

B. The parties hereby agree that changes effected by this modification constitute both the consideration and the equitable adjustment due under any clause of this agreement resulting from the incorporation of the proposal identified in A.3.

C. All other terms and conditions remain the same and in full force and effect.

P00002

A. This modification is being issued to incorporate efforts delineated in proposal revision

(b) (4),

hereby effecting the following changes:

1. JHU is hereby authorized to proceed with efforts identified in the proposal to initiate (b) (4) completion.
2. Funding for the above efforts is available under (b) (4) CLIN 0001.
3. JHU shall submit cost data for review to support line items (b) (4) within 60 days of the effective date of this change order.

B. As stipulated in the proposal, efforts identified shall be executed at no additional cost. Budget revisions identified in paragraph A are hereby incorporated.

C. Appendix A of the agreement shall be revised to incorporate those efforts described in the submission stated in Paragraph A.

D. All other terms and conditions of the contract remain unchanged and in full force and effect.

P00003

A. The purpose of this modification is as follows:

1. CLIN 0001 is hereby increased by (b) (4), from (b) (4), to (b) (4).
2. Appendix A of the Agreement is hereby revised to incorporate efforts identified in proposal dated 2 Oct 2020.
3. Costs incurred (b) (4) shall be submitted in sufficient detail to provide effective oversight, prior to invoicing.
4. Incremental funding for the additional effort is hereby incorporated (b) (4), increasing funding (b) (4), to (b) (4).

B. Appendix D of the Agreement is hereby revised to identify Government Furnished Equipment as follows:

	(b) (4)		
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]



P00005

- A. The purpose of this modification is to definitize costs identified in modification P00004, (b) (4)  
[REDACTED]
- B. The parties hereby agree that changes effected by this modification constitute both the consideration and the equitable adjustment due under any clause of this agreement resulting from the incorporation of the proposal indentified in A.1 above.
- C. All other terms and conditions remain the same and in full force and effect.

Section B - Supplies or Services and Prices

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0001	COVID-19 Human Coronavirus Immune Plasma COST COVID-19 Human Coronavirus Immune Plasma (HCIP) development in accordance with the statement of work contained in Appendix A of the agreement. FOB: Destination PSC CD: AN12		Job		(b) (4)
				ESTIMATED COST	(b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000101	Funding FY 20 COST PURCHASE REQUEST NUMBER: 0011506901-0001				
	ACRN AA CIN: GFEB001150690100010			ESTIMATED COST	\$0.00 (b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000102	FY 20 Funding FFP PURCHASE REQUEST NUMBER: 0011506901-0003				
	ACRN AA CIN: GFEB001150690100010			NET AMT	\$0.00 (b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000103	Funding COST PURCHASE REQUEST NUMBER: 0011506901-0004				
	ACRN AA CIN: GFEBS001150690100010			ESTIMATED COST	\$0.00 (b) (4)

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000104	FY 21 Funding COST PURCHASE REQUEST NUMBER: 0011506901-0007				
	ACRN AA CIN: GFEBS001150690100010			ESTIMATED COST	\$0.00 (b) (4)



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
000102	N/A	N/A	N/A	N/A
000103	N/A	N/A	N/A	N/A
000104	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	28-MAY-2021		N/A FOB: Destination	
000101	N/A	N/A	N/A	N/A
000102	N/A	N/A	N/A	N/A
000103	N/A	N/A	N/A	N/A
000104	N/A	N/A	N/A	N/A

Section G - Contract Administration Data

AGREEMENT ADMINISTRATION

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

B. The telephone number and e-mail addresss of the Agreement Officer and Agreement Specialist are:

Other Transaction Agreements Officer (OTAO)

(b) (6)

ACC-APG-Fort Detrick  
110 Thomas Johnson Dr.  
Frederick, MD 21702

(b) (6)

(b) (6)

Other Transaction Agreement Specialist (OTAS)

(b) (6)

ACC-APG-Fort Detrick  
110 Thomas Johnson Dr.  
Frederick, MD 21702

(b) (6)

(b) (6)

C. Government Agreements Officer Representative (AOR):

(b) (6)

Senior Scientists  
JPM CBRN Medical  
JPEO CBRND  
Frederick, MD

(b) (6)

(b) (6)

ACCOUNTING AND APPROPRIATION DATA

AA: 09720202021013000018170552520252 S.0074658.2.1.1 6100.9000021001

COST CODE: AHPDD

AMOUNT: (b) (4)

ACRN	CLIN/SLIN	CIN	AMOUNT
AA	000101	GFEB001150690100010	\$16,620,625.00
	000102	GFEB001150690100010	\$18,429,698.00
	000103	GFEB001150690100010	\$10,531,251.00
	000104	GFEB001150690100010	\$1,801,249.00

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:

(1) Document type. The Contractor shall submit payment requests using the following document type(s):

(i) For cost-type line items, including labor-hour or time-and-materials, submit a cost voucher.

(ii) For fixed price line items—

(A) That require shipment of a deliverable, submit the invoice and receiving report specified by the Contracting Officer.

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(Contracting Officer: Insert applicable invoice and receiving report document type(s) for fixed price line items that require shipment of a deliverable.)

(B) For services that do not require shipment of a deliverable, submit either the Invoice 2in1, which meets the requirements for the invoice and receiving report, or the applicable invoice and receiving report, as specified by the Contracting Officer.

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(Contracting Officer: Insert either “Invoice 2in1” or the applicable invoice and receiving report document type(s) for fixed price line items for services.)

(iii) For customary progress payments based on costs incurred, submit a progress payment request.

(iv) For performance based payments, submit a performance based payment request.

(v) For commercial item financing, submit a commercial item financing request.

(2) Fast Pay requests are only permitted when Federal Acquisition Regulation (FAR) 52.213-1 is included in the contract.

[Note: The Contractor may use a WAWF “combo” document type to create some combinations of invoice and receiving report in one step.]

(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 By DoDAAC	W56XNH

(\*Contracting Officer: Insert applicable DoDAAC information. If multiple ship to/acceptance locations apply, insert “See Schedule” or “Not applicable.”)

(\*\*Contracting Officer: If the contract provides for progress payments or performance-based payments, insert the DoDAAC for the contract administration office assigned the functions under FAR 42.302(a)(13).)

(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) Receiving report. The Contractor shall ensure a receiving report meets the requirements of DFARS Appendix F.

(g) WAWF point of contact.

(1) The Contractor may obtain clarification regarding invoicing in WAWF from the following contracting activity’s WAWF point of contact.

(b) (6)

(b) (6)

(b) (6)

(2) Contact the WAWF helpdesk at 866-618-5988, if assistance is needed.

(End of clause)