AWARD/CONTRACT

1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)	RATING	PAGE OF PAGES
		1 | 9

2. CONTRACT (Proc. Inst. Ident.) NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQUEST/PROJECT NO.
W911QY2190014	31 Dec 2020	0011590433-0001

5. ISSUED BY	CODE	6. ADMINISTERED BY (If other than Item 5)	CODE
W6QK ACC-APG NATICK DIVISION BLDG 1 GENERAL GREENE AVENUE NATICK MA 01760-5011	W911QY	W6QK ACC-APG NATICK DIVISION 110 THOMAS JOHNSON DR SUITE #240 FREDERICK MD 21702	W911QY

7. NAME AND ADDRESS OF CONTRACTOR (No., street, city, county, state and zip code)	8. DELIVERY	10. SUBMIT INVOICES	ITEM
PHARM-OLAM, LLC 450 N SAM HOUSTON PKWY E STE 250 HOUSTON TX 77060-3556	[ ] FOB ORIGIN [X] OTHER (See below) 9. DISCOUNT FOR PROMPT PAYMENT	(4 copies unless otherwise specified) TO THE ADDRESS SHOWN IN:	

CODE 8NX54	FACILITY CODE

11. SHIP TO/MARK FOR	CODE	12. PAYMENT WILL BE MADE BY	CODE
See Schedule		DEFENSE FINANCE AND ACCOUNTING SERVICE DFAS-INDY VP GFEBS 8899 E 56TH STREET INDIANAPOLIS IN 46249-3800	HQ0490

13. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION:	14. ACCOUNTING AND APPROPRIATION DATA
[ ] 10 U.S.C. 2304(c)( ) [ ] 41 U.S.C. 253(c)( )	See Schedule

15A. ITEM NO.	15B. SUPPLIES/ SERVICES	15C. QUANTITY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT
	SEE SCHEDULE				

15G. TOTAL AMOUNT OF CONTRACT **$36,286,158.00**

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(X)	SEC.	DESCRIPTION	PAGE(S)	(X)	SEC.	DESCRIPTION	PAGE(S)
		PART I - THE SCHEDULE				**PART II - CONTRACT CLAUSES**	
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X	B	SUPPLIES OR SERVICES AND PRICES/ COSTS	2			**PART III – LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACH.**	
	C	DESCRIPTION/ SPECS/ WORK STATEMENT			J	LIST OF ATTACHMENTS	
	D	PACKAGING AND MARKING				**PART IV - REPRESENTATIONS AND INSTRUCTIONS**	
X	E	INSPECTION AND ACCEPTANCE	3		K	REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS	
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X	G	CONTRACT ADMINISTRATION DATA	5 - 8		M	EVALUATION FACTORS FOR AWARD	
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CONTRACTING OFFICER WILL COMPLETE ITEM 17 (SEALED-BID OR NEGOTIATED PROCUREMENT) OR 18 (SEALED-BID PROCUREMENT) AS APPLICABLE

17. [ ] CONTRACTOR'S NEGOTIATED AGREEMENT Contractor is required to sign this document and return copies to issuing office.) Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any continuation sheets for the consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the following documents: (a) this award/contract, (b) the solicitation, if any, and (c) such provisions, representations, certifications, and specifications, as are attached or incorporated by reference herein. (Attachments are listed herein.)

18. [ ] SEALED-BID AWARD (Contractor is not required to sign this document.) Your bid on Solicitation Number _____ including the additions or changes made by you which additions or changes are set forth in full above, is hereby accepted as to the 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)
	(b) (6) (b) (6)

19B. NAME OF CONTRACTOR	19C. DATE SIGNED	20B. UNITED STATES OF AMERICA	20C. DATE SIGNED
BY _____ (Signature of person authorized to sign)		BY . (Signature of Contracting Officer)	31-Dec-2020

Section B - Supplies or Services and Prices

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0001			Job		$36,286,158.00

Prototype Clinical Trial
CPFF
Conduct of a randomized, (b) (4) study of (b) (4) therapeutic (b) (4) adult patients with COVID-19 disease in an outpatient setting. The objective of this prototype project is to evaluate the technical feasibility of this treatment in support of a U.S. Food and Drug Administration (FDA) Emergency Use Authorization (EUA) and/or licensure of the adalimumab for this new indication against COVID-19, in accordance with the Awardee's statement of work, Appendix A of the Agreement.
FOB: Destination
PSC CD: AC12

ESTIMATED COST	(b) (4)
FIXED FEE	(b) (4)
TOTAL EST COST + FEE	$36,286,158.00

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000101					$0.00

FY20 Funding
FFP
PURCHASE REQUEST NUMBER: 0011590433-0001

NET AMT	$0.00
ACRN AA	$36,286,158.00

CIN: GFEBS001159043300001

Section E - Inspection and Acceptance

INSPECTION AND ACCEPTANCE TERMS

Supplies/services will be inspected/accepted at:

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

Section F - Deliveries or Performance

DELIVERY INFORMATION

CLIN	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
0001	30-JUN-2022		N/A FOB: Destination	
000101	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.
B. The telephone number and e-mail addresss of the Agreement Officer and Agreement Specialist are:
Government Representatives:
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)

ACCOUNTING AND APPROPRIATION DATA

AA: 097202020210130000181704464642 55 S.0074658.3.1.3 6100.9000021001
COST CODE: AHPDD
AMOUNT: $36,286,158.00

ACRN	CLIN/SLIN	CIN	AMOUNT
AA	000101	GFEBS001159043300001	$36,286,158.00

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.

_____

(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.

_____

(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*

Field Name in WAWF	*Data to be entered in WAWF*
Pay Official DoDAAC	HQ0490
Issue By DoDAAC	W911QY
Admin DoDAAC**	W911QY
Inspect By DoDAAC	W56XNH
Service Approver (DoDAAC)	W56XNH
Service Acceptor (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)

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

(End of clause)

Section I - Contract Clauses

CLAUSES INCORPORATED BY REFERENCE

52.204-25	Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment.	AUG 2020

OTHER TRANSACTION AUTHORITY
FOR PROTOTYPE
AGREEMENT

BETWEEN

Pharm-Olam, LLC (Awardee)
451 N Sam Houston Pkwy E, Ste 250
Houston, TX, 77060-3556
DUNS: 117578942
CAGE: 8NX54
And
NATICK CONTRACTING DIVISION (Government)
110 Thomas Johnson Dr.
Frederick, MD 21702

Effective Date: 31 Dec 2020

Agreement No.: W911QY-21-9-0014

Total Amount of the Agreement: $36,286,158.00

(b) (6)

Signature

(b) (6)

Printed Name

Chief Financial Officer

Title

December 30, 2020

Date

(b) (6)

Signature

(b) (6)

Printed Name

Agreements Officer

Title

31 Dec 2020

Date

This Other Transaction Authority for Prototype Agreement is entered into between the United States of America, hereinafter called the "Government", pursuant to and under U.S. Federal law and Pharm-Olam, LLC, a non-traditional defense contractor, hereinafter called the "Awardee". The United States of America and Awardee are sometimes referred to herein individually as a "Party" and collectively as the "Parties."

WHEREAS, the Awardee is eligible for an Other Transaction Authority for Prototype Agreement in accordance with 10 USC § 2371b(d)(1)(A) as amended by the National Defense Authorization Act for Fiscal Year 2018 as they are non-traditional defense contractor, attesting to "An entity that is not currently performing and has not performed, for at least the one-year period preceding the solicitation of sources by the Department of Defense for the procurement or transaction, any contract or subcontract for the Department of Defense that is subject to the full coverage under the cost accounting standards prescribed pursuant to Section 1502 of title 41 and the regulations implementing such section.";

WHEREAS, the DoD currently has authority under 10 U.S.C. § 2371b to award "other transactions" (OTs) in certain circumstances for prototype projects that are directly relevant to enhancing the mission effectiveness of military personnel and the supporting platforms, systems, components, or materials proposed to be acquired or developed by the DoD, or to improve platforms, systems, components, or materials in use by the Armed Forces;

WHEREAS, a prototype can generally be described as a physical or virtual model used to evaluate the technical or manufacturing feasibility or military utility of a particular technology or process, concept, end item, or system;

WHEREAS, this Agreement meets the criteria for a prototype project;

NOW THEREFORE, the Parties have agreed as follows:

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. §§ 200-12.

B. The Parties agree that the ultimate purpose of this Agreement is the conduct of a randomized, adaptive placebo-controlled Phase II/III clinical study of the anti-TNFα therapeutic (Humira® [adalimumab] 160 mg) in adult patients with COVID-19 disease in an outpatient setting. The objective of this prototype project is to evaluate the technical feasibility of this treatment in support of a U.S. Food and Drug Administration (FDA) Emergency Use Authorization (EUA) and/or licensure of the adalimumab for this new indication against COVID-19, (hereinafter referred to as the "Prototype Project" or "Prototype"). A Prototype may be a clinical trial, a demonstration of efficacy or safety, or other process, or a combination of the foregoing in defense of SARS-CoV-2/COVID-19. This Prototype Project is a combination of an agile development activity, design, and demonstration of the technical and operational utility of a product to move forward as an FDA-approved therapeutic against COVID-19. The Awardee shall develop the Prototype(s) as described in the Awardee's Statement of Work (SOW), which is incorporated herein and attached hereto as Appendix A

C. The prototype will be deemed successful upon the Government's determination that the Awardee's efforts meet the key technical requirements of the SOW and are sufficient to meet an FDA compliant final report(s) that supports the completion of a human clinical trial(s). In accordance with 10 U.S.C. 2371b(f), this competitively awarded prototype OTA is not expected to result in the award of a follow-on production contract or transaction.

ARTICLE 2. Term and Termination.

A. Term: The Term of this Agreement commences upon the Effective Date and extends through final payment. This Agreement is anticipated to end (b) (4) months after the Effective Date, subject to completion of the project(s). 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, or (2) accomplished a particularly favorable or unexpected result that justifies the completion of the prototype.

B. Termination for Convenience: The Government may terminate this Agreement for any or no reason by providing at least thirty (30) calendar days' prior written notice to the Awardee. 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.

C. 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 ten (10) business days

or the time allowed by the OTAO after Awardee's receipt of the cure notice, whichever is longer, may take one or more of the following actions as appropriate:

(i) temporarily withhold payments pending correction of the deficiency,
(ii) disallow all or part of the cost of the activity or action not in compliance,
(iii) wholly or partly suspend or terminate this Agreement,
(iv) withhold further funding, or
(v) take any other legally available remedies.

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.

D. 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 (GPM)

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 completion or acceptance of the effort by the Government. The key personnel listed in Appendix C 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 with an opportunity to approve, the approval of which will not be unreasonably withheld. 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.

D. Subaward Approval: Modifications to subawards and/or new subcontracts under this Agreement that could reasonably impact the technical approach proposed and accepted by the Government require the approval of the OTAO prior to being executed.

E. The OTAO has assigned an Agreements Officer's Representative (AOR) for this agreement. The Awardee will receive a copy of the written designation outlining the roles and responsibilities of the AOR and specifying the extent of the AOR's authority to act on behalf of the OTAO. The AOR is not authorized to make any commitments or changes that will affect price, quality, quantity, delivery, or any other term or condition of the contract.

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 OTAO be effective or binding upon the Government. All such actions must be formalized by a proper contractual document executed by the OTAO.

Government Representatives:

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)

Agreements Officer Representative (AOR):

(b) (6)
COVID-19 Repurposing PM
Joint Project Manager - Chemical, Biological, Radiological, and Nuclear Medical (JPM CBRN Medical)
1564 Freedman Drive
Fort Detrick, MD 21702
(b) (6)

Awardee Representatives:

(b) (6)
Vice-President US Government Contracts, Proposals, and Business Development Pharm-Olam, LLC
79 TW Alexander Dr.
BLD 4401, Suite 240
Research Triangle Park, NC 27709
(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 OTAO. 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 OTAO and made part of this Agreement. Any modification to this Agreement to account for recommended changes in the SOW or Payable Milestones will be considered a supplemental agreement.

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

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 OTAO. The OTAO will review the matter and render a decision in writing within sixty (60) calendar days. Thereafter, 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 by mutual consent to explore and establish and Alternate Disputes Resolution procedure to resolve this dispute. The Awardee shall proceed diligently with performance under this agreement pending resolution of the dispute.

ARTICLE 6. Inspection/Acceptance

A. Inspection: The Government has the right to inspect and test all work called for by this Agreement, to the extent practicable at all places and times, including the period of performance, and in any event before acceptance. The Government may also inspect the premises of the Awardee or any subawardee engaged in 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 or a subawardee, the Awardee shall furnish and shall require subawardees to furnish, at no increase in 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 or subawardee's premises.

B. The Government shall inspect/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. Inspection/Acceptance of the Prototype performed should not exceed 90 days after completion.

ARTICLE 7. Financial Matters

This Agreement is an expenditure type Other Transaction Authority agreement. The payments provided under this Agreement are intended to compensate the Awardee on a cost basis for performance under this Agreement. The Awardee shall provide its best efforts to complete a prototype project based on the estimated cost. Payments are based on amounts generated from the Awardee's financial or cost records.

A. Payment. Payments are based on amounts generated from the Awardee's financial or cost records. The Awardee shall be reimbursed for each element identified in the awarded cost proposal, executed and accomplished in accordance with the performance schedule set forth in Appendix B. The schedule is predicated upon the Government's fiscal year, which begins on October 1 of each year, and ends on September 30 of the subsequent 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. The Government may 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, the costs stipulated in this Agreement for work delivered or rendered and accepted, less any deductions provided in this Agreement. Unless otherwise specified, payment shall be made upon acceptance of any portion of the work delivered or rendered for which a price is separately stated in the Agreement. Payments will be made within thirty (30) calendar days of receipt of a request for payment.

E. Prior written approval by the OTAO, or the AOR, is required for all travel directly and identifiably funded by the Government under this agreement. The Awardee shall present to the OTAO or AOR, an itinerary for each planned trip, showing the name of the traveler, purpose of the trip, origin/destination, dates of travel, and estimated cost broken down by line item as far in advanced of the proposed travel as possible, but no less than two weeks before travel is planned to commence. In the event that emergency travel is required (e.g. in the event of an outbreak) that would make two weeks' notice impractical, travel requests may be submitted to the Government for an expedited review. Emergency travel requests shall be labelled as such and shall include a brief summary of the emergency situation and rationale for expedited review.

F. 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 Agreement:

(1) Document type. The Awardee shall use the following document type: 2 in 1 combo.

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

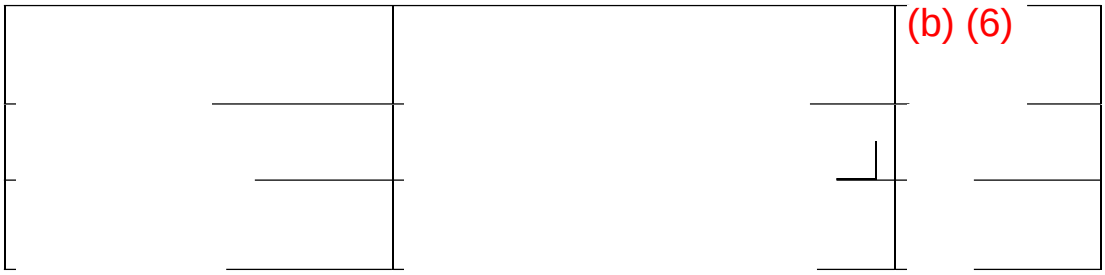
(3) Document routing. The Awardee shall use the information in the Routing Data Table below only to fill in applicable fields in WAWF when creating payment requests and receiving reports in the system.

Routing Data Table

Field Name in WAWF	***Data to be entered in WAWF***
Pay Official DoDAAC	**HQ0490**
Issue By DoDAAC	**W911QY**
Admin DoDAAC	**W911QY**
Inspect By DoDAAC	**W56XNH**

(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, costs, 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.



(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)

G. 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

1. 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 JPEO JPM CBRN Medical.

2. Quarterly Progress Reports

The Awardee shall submit a Quarterly Progress report within twenty (20) 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 OTAO 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 five (5) calendar days to revise the deliverable or respond to those comments.

3. Monthly Financial Status Report

The Awardee shall submit a Monthly Financial Status Report no later than twenty (20) 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 Awardee will

have an additional ten (10) calendar days to revise the deliverable or respond to those comments. Reports will cover work performed every month for the duration of the Period of Performance (PoP).

In addition, the monthly Financial Status Report shall include monthly expenditure forecasts with both the monthly 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.

4. 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 fifteen (15) 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.

5. 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 (45^{th}) calendar day following the end of the project. The Government shall provide comments to the Awardee by the thirtieth (30^{th}) calendar day following receipt of the Awardee's Draft Final Report. The Awardee shall submit the Final Report on the thirtieth (30^{th}) calendar day after receipt.

6. 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. The Awardee shall provide meeting minutes within three (3) business days after each ad hoc meeting/teleconference conducted with JPEO JPM CBRN Medical.

7. 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).

8. Miscellaneous Data Submissions

If applicable, the 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, United States Army Medical Research and Development Command Human Research Protection Office (HRPO) 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. Examples include clinical performance and clinical quality documentation.

9. 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.

10. 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 five (5) calendar days to revise the deliverable or respond to those comments.

11. Incident Report.

The Awardee shall report any incident to the Government that could result in any 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.

13. Source Material Reports

The Awardee shall submit a detailed spreadsheet regarding critical project materials that are sourced from a location other than the United States, sources, including but not limited to: physical locations of sources material by type of material (e.g., software, testing, analytical and environmental componentry, reagents) and location and nature of clinical study sites.

14. Awardee Locations

The Awardee shall submit detailed data regarding locations where work will be performed under this Agreement, including addresses, points of contact, and work performed per location, to include sub-awardees.

Awardee will submit Work Locations Report:

- Within 5 business days of Agreement award
- Within 30 business days after a substantive location or capabilities change
- Within 2 business days of a substantive change if the work performed supports medical countermeasure development that addresses a threat that has been declared a Public Health Emergency by the HHS Secretary or a Public Health Emergency of International Concern (PHEIC) by the WHO

ARTICLE 9. Confidential Information

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

b. The Contracting Officer and the Contractor may, by mutual consent, identify elsewhere in this

contract specific information and/or categories of information which the Government will furnish to the Contractor or that the Contractor is expected to generate which is confidential. Similarly, the Contracting Officer and the Contractor may, by mutual consent, identify such confidential information from time to time during the performance of the contract. Failure to agree will be settled pursuant to the "Disputes" clause.

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

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

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

f. Contracting Officer Determinations will reflect the result of internal coordination with appropriate program and legal officials.

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

All above requirements MUST be passed to all Sub-contractors.

ARTICLE 10. Intellectual Property Rights

A. Awardee represents that the rights held by or granted to Awardee, including all intellectual property licenses, are sufficient to enable Awardee to perform its obligations under this Agreement.

B. Background IP and Materials. The Awardee and the Government each retain any intellectual property (IP) rights to their own materials, data, technology, information, documents, or know-how—or potential rights, such as issued patents, patent applications, invention disclosures, or other written documentation—that exist prior to execution of this Agreement or are developed outside the scope of this Agreement ("Background IP"). Additionally, no party to the 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 Subject Data, as those terms are defined in this Agreement, absent the mutual consent of the parties to the awarded contract.

C. Awardee's Background IP. Awardee warrants that it has filed patent application(s) or is the assignee of issued patent(s) listed below which contain claims that are related to research contemplated under this Agreement. No license(s) to any patent applications or issued patents shall be granted under this Agreement, and the application(s) and any continuing applications (except for continuing applications pursuant to this agreement) are specifically excluded from the definitions of "OTA Invention" contained in this Agreement: None.

D. Government's Background IP. The government warrants that it has no Background IP and therefore lists "None".

E. Patent Indemnity. The Awardee shall indemnify the Government and its officers, employees and agents against liability, including costs, for actual or alleged direct or contributory infringement of, or inducement to infringe, any United States or foreign patent, trademark or copyright, arising out of this Agreement, provided the Awardee is reasonably notified of such claims and proceedings.

F. 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 the work performed under this Agreement. Awardee shall keep the Government reasonably advised on the status of Awardee Background IP by providing an annual 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.

G. Patent Applications. Each Party shall report any Agreement Inventions to the other Party within 60 days of the time the inventor discloses it in writing to its personnel responsible for patent matters. 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 forty-five (45) calendar days 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.

H. 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

I. OTA Inventions. Ownership of any invention, regardless of whether it is not patentable, 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 an OTA Invention, the entire rights to that OTA Invention will be assigned to the Government. If an Awardee employee and a Government employee jointly make an OTA invention, the Awardee's interest will be assigned by the Awardee to the Government and owned by the Government.

F. 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 by a Government employee.

G. 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.

H. The Government shall flow down the requirements of this Article 10 to their respective personnel, member entities, agents, and Awardees (including employees) at all levels, under this Agreement.

ARTICLE 11. Data Rights

A. Background Data. "Background Data" shall mean all technical data, as defined in DFARS 252.227-7013 that exists prior to execution of this Agreement, or are developed outside the scope of this Agreement. Recipient's Background Data includes, but is not limited to, the following technical data, to the extent such data exists prior to execution of this Agreement or is developed outside the scope of this Agreement: [None Reported].

B. Subject Data. All data generated in connection with the performance of 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 "Subject Data"), shall be owned by the Awardee. The Government shall have the right to use, modify, reproduce, release, perform, display, or disclose Subject Data within the Government and otherwise for "Unlimited rights," as this term is defined in DFARS 252.227-7013(a)(16). The Government may, under a separate agreement or by modification to this agreement, obtain any rights to use or disclose the Awardee's Background Data to the extent that such material or data was produced outside the scope of this Agreement.

C. The Awardee agrees to retain and maintain in good condition until seven (7) 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 paragraph 2.C, the Awardee agrees to deliver at no additional cost to the Government, 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.

D. Marking of Data: The Awardee will mark any data delivered under this Agreement with the following legend:

"Use, duplication, or disclosure is subject to the restrictions as stated in Agreement No. W911QY-21-9-0014 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.

E. All Subject Data meeting the definitions of "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 drugs, biologics or medical devices that are regulated by the FDA and require FDA pre-market approval or clearance before

commercial marketing may begin for the COVID-19 indication. The Parties anticipate that for the Prototype Project(s) contemplated under this Agreement, the Awardee or its designated subawardee will serve as the Sponsor of the Regulatory Application (an investigational new drug application (IND), investigational device exemption (IDE), new drug application (NDA), biologics license application (BLA), premarket approval application (PMA), or 510(k) pre-market notification filing (510(k)) or another regulatory filing submitted to FDA) that will control research under this Agreement. The Sponsor of the Regulatory Application to FDA (as the terms "sponsor", "sponsor-investigator", 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), has certain standing before the FDA that entitles him to exclusive communications related to the Regulatory Application.

Regarding any Technology developed under this agreement for which Awardee or its designated subawardee serves as regulatory Sponsor, the Awardee agrees to the following, which will flow down to appropriate subcontractors performing regulatory functions:

a. Government Regulatory Representatives: The Senior Director Medical Regulatory (SDMR) is the JPEO-CBRND representative for all regulatory and quality activities. The Awardee shall coordinate with the SDMR prior to communicating or meeting with the FDA, or other regulatory authorities, as appropriate. The Awardee shall invite the SDMR to all FDA meetings if applicable and regulatory discussions applicable to this Agreement.
    1. The regulatory Sponsor shall submit a letter to FDA indicating the SDMR as a co-contact and that FDA is authorized to contact SDMR for DoD regulatory/policy input, as needed for this development effort. This notice could be part of the PL 115-92 authorization letter described below. In this circumstance and to the maximum extent practicable, the Government will include the Sponsor in any and all meetings and correspondence with the FDA. If it is not practicable to include the Sponsor in any interaction with the FDA, the Government will provide a summary of the interaction to the Sponsor within ten (10) business days.
    2. Non-compliance with section (a) may result in termination of the Agreement.

b. Regulatory Submissions. The Awardee will provide to the Government all data, including top-line summaries and key conclusions from all studies supporting the regulatory filing and commercial approval to the extent that such data, summaries, and conclusions are funded by this Agreement. In addition, the Awardee will offer the Government the opportunity to review and provide comments on a final draft of regulatory submissions, which include data funded by this Agreement. The Government will review any such submissions (i.e., the IND) promptly upon receipt. The Awardee will reasonably consider any comments provided by the Government, and prior to

submission will provide notification to the Government of any additional edits or revisions. The Awardee will keep the Government apprised of planned FDA meetings and post-meeting outcomes relating to activities funded by this Agreement.

c. Communications. The Awardee shall provide the Government with all material communications and summaries thereof, both formal and informal, to or from FDA, regarding the Technology within 48 hours, and ensure that the Government representatives are invited to participate in any formal or informal Sponsor meetings with FDA. Awardee shall (1) ensure that the Government representatives are consulted and are invited to participate in any formal or informal Sponsor meetings with FDA related to the Technology; and (2) notify the FDA that the Government has the right to discuss with FDA any development efforts regarding the Technology.

d. Rights of Reference. Awardee hereby grants to the Government and its permitted sublicensees a limited "right of reference or use" (as that term is defined in 21 C.F.R. § 314.3(b), as amended from time to time) to Awardee's filings to the FDA in connection with the Regulatory Application strictly for COVID-19 or other Material Threat (as defined at Section 319 of the Public Health Service Act) purposes. The Awardee shall provide appropriate notification of the Government's access and reference rights to the applicable regulatory authorities requested by the Government for the limited purposes described above. Awardee agrees to provide a letter of cross-reference to the Government and file such letter with the appropriate FDA office. The Government will agree to any reasonable request for information connected to its reliance on the right of reference provided under this Section. This provision is in addition to any rights in technical data described earlier in this document.

e. Product Development Failure. Certain product development failures may trigger certain remedies in this section for the Government advanced developer funding the development of this Technology.

1. This remedy is only available to the Government if and when any of the following conditions occur:
    i. this Agreement is terminated for nonperformance; or
    ii. the Awardee gives notice, required to be submitted to the Government no later than 30 business days, of any formal management decision to terminate the prototype project;
    iii. the Awardee gives written notice, required to be submitted to the Government no later than 30 business days, of any filing that anticipates Federal bankruptcy protection.
2. If any of the product development failures listed above occur, the Awardee, upon the request of the Government:
    i. Shall transfer possession, ownership and sponsorship or holdership of any Regulatory Application (including any associated expedited review designation, priority review voucher, or marketing

exclusivity eligibility or award), regulatory correspondence, and supporting regulatory information related to the Technology to the Government or its designee;

ii. Shall inform FDA of the transfer of sponsorship or holdership of the Regulatory Application transferred under section (2)(i) above; and

iii. Shall negotiate in good faith and upon fair and reasonable terms a non-exclusive license to any patent, copyright, Technical Data or other intellectual property owned or controlled by the Awardee, developed prior to or outside the scope of this Agreement that is necessary for the Government to pursue commercialization of the Technology, with a third party for sale to the Government or otherwise.

3. This clause will survive the acquisition or merger of the Awardee by or with a third party. This clause will also be included in any subcontracts/subawards relating to the development of the Technology. This clause will survive the expiration of this Agreement.

f. Public Law 115-92 Sponsor Authorization Letter/ DoD Medical Product Priority: Public Law 115-92 allows the DoD to request, and FDA to provide, assistance to expedite development 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 Public Law 115-92. As such, the Awardee will work proactively with the SDMR to leverage this law to its maximum potential under this Agreement.

1. The Awardee shall submit to the Government, within thirty (30) days of project award, a fully executed sponsor authorization letter enabling FDA to disclose information to JPEO-CBRND and its Government support contractors related to the proposed product under Public Law 115-92. A template for the sponsor authorization letter was included in Appendix E.
2. JPEO-CBRND shall formally submit the executed letter to the FDA under the Regulatory Application, only if the proposed product becomes a DoD medical product priority under Public Law 115-92.
3. If the product becomes a DoD medical product priority, to the maximum extent practicable, JPEO-CBRND will include the Awardee in any and all meetings and correspondence conducted with the FDA under Public Law 115-92. If it is not practicable to include the Awardee in any Public Law 115-92 interaction with the FDA regarding the product (for example, discussions conducted at quarterly or semi-annual DoD-FDA meetings mandated by the Public Law), JPEO-CBRND will provide a summary of the interaction to the Awardee within ten (10) business days.

g. Regulatory Compliance:

1. **cGCP Compliance**. Awardee shall maintain clinical development and operations as required to ensure proper clinical testing, operations, data management, biostatistical evaluation, clinical supply, and other capabilities required to ensure full compliance with Good Clinical Practices (GCP).
2. **Drug Supply Chain Security Act**. The provision of doses of the Protoype Project will be compliant with applicable provisions of the Drug Supply Chain Security Act (DSCSA) Sections 581-585 of PL 113-54 (Nov 27, 2013), taking into account FDA's regular guidance for the public health response.

h. Flow Down: The Awardee shall flow down the requirements of this Article 12 to its subawardee.

ARTICLE 13. Foreign Access to Data.

A. 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. Public Affairs and Operational Security Review: All manuscripts, press releases, presentations and other publications will be provided to the JPEO-CBRND Public Affairs Office (PAO) allowing for review/approval in accordance with Article 9.04(i) and (ii) above prior to use or release. Per JPEO-CBRND regulation the PAO review will include Operational Security (OPSEC) review.

B. The Parties shall jointly agree on a publication plan for the Study Data derived from studies executed under this Agreement. This publication 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.

C. Scientific publication regarding Study results in any form, including, without limitation, manuscript(s), abstracts, posters, slides, or other materials used for presentations ("Scientific Publication"): Prior to either Party submitting a Scientific Publication for publication which contains the results of the Study under this Agreement, each Party shall notify the other Party in writing of the proposed Scientific Publication, offer ample opportunity to review proposed Scientific Publication, and to file patent applications in a timely manner (if applicable), provided that the review period is at least thirty (30) days from receipt of the draft Scientific Publication and the filing period is at least an additional sixty (60) days from the end of the review period. The Parties agree that authorship related to Scientific Publications shall be determined

in accordance with and governed by the criteria defined by the International Committee of Medical Journal Editors (ICMJE) "Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals." The Parties also agree to give appropriate credit to the entity responsible for the Study performed and to disclose Cooperator's role in support of the Study. The publishing Party shall keep the proposed Scientific Publication confidential for the entire review period and, if applicable, the patent filing period, and shall delete the other Party's Proprietary Information (other than the results of the Study generated hereunder) from the Scientific Publication upon request.

D. The Parties will jointly develop each abstract or manuscript and agree on the 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.

E. 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.

F. The Parties will jointly agree on whether to issue one or more press releases related to the resulting Data. If all Parties agree that one or both Parties will issue a press release, each Party will also have the right to review and agree on the content in advance of its publication. 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.

G. Press releases: Prior to any such release containing the Study results or other information about the Study performed under this Agreement, Parties agree to provide written notification and ample opportunity (at least five business days) for review to the other Party; provided that each Party will use best efforts to complete its review of proposed press releases in a shorter period of time if the Party initiating the press release identifies the need for an urgent review. Comments and approval by each

Party shall be prior to release.

ARTICLE 15. Human Subjects.

(a) Definitions. As used in this clause -

(1) Assurance of compliance means a written assurance that an institution will comply with requirements of 32 CFR Part 219, as well as the terms of the assurance, which the Human Research Protection Official determines to be appropriate for the research supported by the Department of Defense (DoD) component (32 CFR 219.103).

(2) Human Research Protection Official (HRPO) means the individual designated by the head of the applicable DoD component and identified in the component's Human Research Protection Management Plan as the official who is responsible for the oversight and execution of the requirements of this clause, although some DoD components may use a different title for this position.

(3) Human subject means a living individual about whom an investigator (whether professional or student) conducting research (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. (32 CFR 219.102(e)). For example, this could include the use of human organs, tissue, and body fluids from individually identifiable living human subjects as well as graphic, written, or recorded information derived from individually identifiable living human subjects.

(4) Institution means any public or private entity, or department or agency (including federal, state, and other agencies). (32 CFR 219.102(f)).

(5) Institutional Review Board (IRB) means a board established in accord with and for the purposes expressed in 32 CFR Part 219 (32 CFR 219.102(g)).

(6) IRB approval means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and Federal requirements (32 CFR 219.102(h)).

(7) Research means a systematic investigation, including research, development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of 32 CFR Part 219, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities (32 CFR 219.102(l)).

(b) The Awardee shall oversee the execution of the research to ensure compliance with this clause. The Awardee shall comply fully with 32 CFR Part 219 and DoD Instruction 3216.02, applicable DoD component policies, 10 U.S.C. 980, and, when applicable, Food and Drug Administration policies and regulations.

(c) The Awardee shall not commence performance of research involving human subjects that is covered under 32 CFR Part 219 or that meets exemption criteria under 32 CFR 219.104, or expend funding on such effort, until and unless the conditions of either the following paragraph (c)(1) or (c)(2) have been met:

(1) The Awardee furnishes to the HRPO, with a copy to the Agreements Officer, an assurance of compliance and IRB approval and receives notification from the OTAO that the HRPO has approved the assurance as appropriate for the research under the Statement of Work and also that the HRPO has reviewed the protocol and accepted the IRB approval for compliance with the DoD component policies. The Awardee may furnish evidence of an existing assurance of compliance for acceptance by the HRPO, if an appropriate assurance has been approved in connection with previous research. The Awardee shall notify the OTAO immediately of any suspensions or terminations of the assurance.

(2) The Awardee furnishes to the HRPO, with a copy to the OTAO, a determination that the human research proposed meets exemption criteria in 32 CFR 219.104 and receives written notification from the OTAO that the exemption is determined acceptable. The determination shall include citation of the exemption category under 32 CFR 219.104 and a rationale statement. In the event of a disagreement regarding the Awardee's furnished exemption determination, the HRPO retains final judgment on what research activities or classes of research are covered or are exempt under the agreement.

(d) DoD staff, consultants, and advisory groups may independently review and inspect the Awardee's research and research procedures involving human subjects and, based on such findings, DoD may prohibit research that presents unacceptable hazards or otherwise fails to comply with DoD procedures.

(e) Failure of the Awardee to comply with the requirements of this clause will result in the issuance of a stop-work order to immediately suspend, in whole or in part, work and further payment under this Agreement, or will result in other issuance of suspension of work and further payment for as long as determined necessary at the discretion of the OTAO.

(f) The Awardee shall include the substance of this clause, including this paragraph (f), in all subcontracts that may include research involving human subjects in accordance with 32 CFR Part 219, DoD Instruction 3216.02, and 10 U.S.C. 980, including

research that meets exemption criteria under 32 CFR 219.104. This clause does not apply to subcontracts that involve only the use of cadaver materials.

ARTICLE 16. Miscellaneous Clauses.

A. No Consent. Nothing in the terms of this Agreement constitutes express or implied Government authorization and consent for Awardee or its subawardee(s) to utilize, manufacture or practice inventions covered by United States or foreign patents in the performance of work under this Agreement.

B. Patent Infringement. 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.

C. Limitation of Liability. In no event will either Party 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.

D. Disclosure of Information. Subject to Article 10, the Awardee shall not release to anyone outside the Awardee's organization any unclassified information, 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 OTAO has given prior written approval or (ii) the information is otherwise in the public domain before the date of release. For purposes of this clause, Awardee's Organization includes entities identified as Collaborators in Appendix A Table 1.

E. 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.

F. 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.

G. 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.

H. 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.

I. Institutional Responsibility Regarding Investigator Conflicts of Interest

The Institution (includes any Contractor, public or private, excluding a Federal agency) shall comply with the requirements of 45 CFR Part 94, Responsible Prospective Contractors, which promotes objectivity in research by establishing standards to ensure that Investigators (defined as the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded under Government contracts, or proposed for such funding, which may include, for example, collaborators or consultants) will not be biased by any Investigator financial conflicts of interest. 45 CFR Part 94 is available at the following Web site: http://www.ecfr.gov/cgi-bin/textidx?c=ecfr&SID=0af84ca649a74846f102aaf664da1623&rgn=div5&view=text&node=45:1.0.1.1.51&idno=

As required by 45 CFR Part 94, the Institution shall, at a minimum:

a. Maintain an up-to-date, written, enforceable policy on financial conflicts of interest that complies with 45 CFR Part 94, inform each Investigator of the policy, the Investigator's reporting responsibilities regarding disclosure of significant financial interests, and the applicable regulation, and make such policy available via a publicly accessible Web site, or if none currently exist, available to any requestor within five business days of a request. A significant financial interest means a financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

1. With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000. Included are payments and equity interests;
2. With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest; or
3. Intellectual property rights and interests, upon receipt of income related to such rights and interest.

Significant financial interests do not include the following:

1. Income from seminars, lectures, or teaching, and service on advisory or review panels for Government agencies, Institutions of higher education, academic teaching hospitals, medical centers, or research institutes with an Institution of higher learning; and
2. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles.

b. Require each Investigator to complete training regarding the Institution's financial conflicts of interest policy prior to engaging in research related to any Government funded contract and at least every four years. The Institution must take reasonable steps [see Part 94.4(c)] to ensure that investigators working as collaborators, consultants or subcontractors comply with the regulations.

c. Designate an official(s) to solicit and review disclosures of significant financial interests from each Investigator who is planning to participate in, or is participating in, the Government funded research.

d. Require that each Investigator who is planning to participate in the Government funded research disclose to the Institution's designated official(s) the Investigator's significant financial interest (and those of the Investigator's spouse and dependent children) no later than the date of submission of the Institution's proposal for Government funded research. Require that each Investigator who is participating in the Government funded research to submit an updated disclosure of significant financial interests at least annually, in accordance with the specific time period prescribed by the Institution during the period of the award as well as within thirty days of discovering or acquiring a new significant financial interest.

e. Provide guidelines consistent with the regulations for the designated official(s) to

determine whether an Investigator's significant financial interest is related to Government funded research and, if so related, whether the significant financial interest is a financial conflict of interest. An Investigator's significant financial interest is related to Government funded research when the Institution, thorough its designated official(s), reasonably determines that the significant financial interest: Could be affected by the Government funded research; or is in an entity whose financial interest could be affected by the research. A financial conflict of interest exists when the Institution, through its designated official(s), reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the Government funded research.

f. Take such actions as necessary to manage financial conflicts of interest, including any financial conflicts of a subcontractor Investigator. Management of an identified financial conflict of interest requires development and implementation of a management plan and, if necessary, a retrospective review and mitigation report pursuant to Part 94.5(a).

g. Provide initial and ongoing FCOI reports to the Contracting Officer pursuant to Part 94.5(b).

h. Maintain records relating to all Investigator disclosures of financial interests and the Institution's review of, and response to, such disclosures, and all actions under the Institution's policy or retrospective review, if applicable, for at least 3 years from the date of final payment or, where applicable, for the other time periods specified in 48 CFR Part 4, subpart 4.7, Contract Records Retention.

i. Establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator compliance as appropriate.

j. Complete the certification in SAM - Representations, Certifications, and Other Statements of Contractors titled "Certification of Institutional Policy on Financial Conflicts of Interest".

If the failure of an Institution to comply with an Institution's financial conflicts of interest policy or a financial conflict of interest management plan appears to have biased the design, conduct, or reporting of the Government funded research, the Institution must promptly notify the Contracting Officer of the corrective action taken or to be taken. The Contracting Officer will consider the situation and, as necessary, take appropriate action or refer the matter to the Institution for further action, which may include directions to the Institution on how to maintain appropriate objectivity in the Government funded research project.

The Contracting Officer and/or Government may inquire at any time before,

during, or after award into any Investigator disclosure of financial interests, and the Institution's review of, and response to, such disclosure, regardless of whether the disclosure resulted in the Institution's determination of a financial conflict of interests. The Contracting Officer may require submission of the records or review them on site. On the basis of this review of records or other information that may be available, the Contracting Officer may decide that a particular financial conflict of interest will bias the objectivity of the Government funded research to such an extent that further corrective action is needed or that the Institution has not managed the financial conflict of interest in accordance with Part 94.6(b). The issuance of a Stop Work Order by the Contracting Officer may be necessary until the matter is resolved.

If the Contracting Officer determines that Government funded clinical research, whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, has been designed, conducted, or reported by an Investigator with a financial conflict of interest that was not managed or reported by the Institution, the Institution shall require the Investigator involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

k. Organizational Conflicts of Interest

Performance under this contract may create an actual or potential organizational conflict of interest such as are contemplated by FAR Part 9.505-General Rules. The Contractor shall not engage in any other contractual or other activities which could create an organizational conflict of interest (OCI). This provision shall apply to the prime Contractor and all sub-Contractors. This provision shall have effect throughout the period of performance of this contract, any extensions thereto by change order or supplemental agreement, and for two (2) years thereafter. The Government may pursue such remedies as may be permitted by law or this contract, upon determination that an OCI has occurred.

The work performed under this contract may create a significant potential for certain conflicts of interest, as set forth in FAR Parts 9.505-1, 9.505-2, 9.505-3, and 9.505-4. It is the intention of the parties hereto to prevent both the potential for bias in connection with the Contractor‘s performance of this contract, as well as the creation of any unfair competitive advantage as a result of knowledge gained through access to any non-public data or third party proprietary information.

The Contractor shall notify the Contracting Officer immediately whenever it becomes aware that such access or participation may result in any actual or potential OCI. Furthermore, the Contractor shall promptly submit a plan to the Contracting Officer to either avoid or mitigate any such OCI. The Contracting Officer will have sole discretion in accepting the Contractor‘s mitigation plan. In the event the Contracting Officer unilaterally determines that any such OCI cannot be satisfactorily avoided or mitigated, other remedies may be taken to prohibit the Contractor from participating in contract requirements related to OCI.

Whenever performance of this contract provides access to another Contractor‘s proprietary information, the Contractor shall enter into a written agreement with the other entities involved, as appropriate, in order to protect such proprietary information from unauthorized use or disclosure for as long as it remains proprietary; and refrain from using such proprietary information other than as agreed to, for example to provide assistance during technical evaluation of other Contractors’ offers or products under this contract. An executed copy of all proprietary information agreements by individual personnel or on a corporate basis shall be furnished to the CO within fifteen (15) calendar days of execution.

L. FAR 52.204-25 Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment incorporated by reference.

M. The Parties will comply with all applicable Laws regarding Study participant confidentiality and data protection, including, without limitation, HIPAA, HITECH, and applicable state privacy Laws, in the collection, use, storage and disclosure of protected health information (as defined under HIPAA) (“PHI”). Pharm-Olam shall collect, use, store, access and disclose PHI collected from Study participants only in accordance with applicable ICFs or with applicable Laws. Pharm-Olam shall also obtain in the ICF or separate authorization document, permission for USG/USG representatives involved with or evaluating the Study to access and obtain copies of the Subject Data and to otherwise exercise its rights under this Agreement, including, without limitation, its audit rights

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**.**

Statement of Work

Objectives

The objective is the conduct of a randomized, adaptive placebo-controlled Phase II/III clinical study of the anti-TNFα therapeutic (Humira® [adalimumab] 160 mg) in adult patients with COVID-19 disease in an outpatient setting. The goal of this prototype project is to evaluate the technical feasibility of this treatment in support of a U.S. Food and Drug Administration (FDA) Emergency Use Authorization (EUA) and/or licensure of the adalimumab for this new indication against COVID-19,

Period of Performance

Identified in Appendix B of this agreement.

Place of Performance

Multiple sites in CONUS

Requirements

Pharm-Olam will complete the following tasks. Tasks which are not included are subject to revision based on discussions with the US Government:

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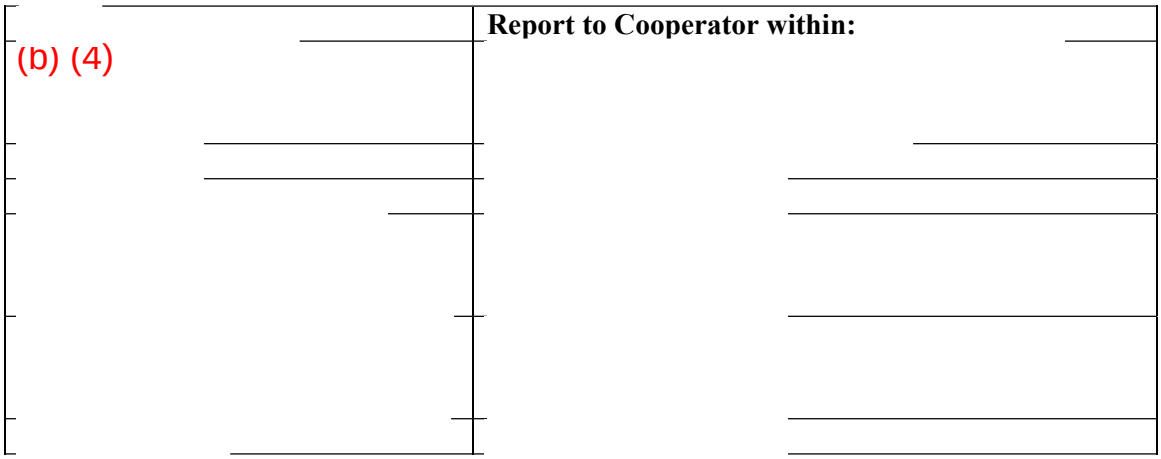


Pharm-Olam shall make or require Study Personnel to make available to USG/USG representatives promptly such records as may be necessary and pertinent to investigate any Safety Information, if specifically required by USG.

For purposes of this Agreement, (i) "**Adverse Event**" means any untoward medical occurrence in a Study participant administered the Study Product and which does not necessarily have a causal relationship with the Study or Study Product; (ii) **"Safety Signal"** means any event in the Study that potentially signals (i) a new causal association with the Study Product or (ii) a new aspect of a known association with the Study Product; (iii) "**Serious Adverse Event**" means any event that results in any of the following: (A) death; (B) a life-threatening adverse drug experience (i.e., the Study participant was at immediate risk of death from the event as it occurred); (C) a persistent or significant disability/incapacity; (D) inpatient hospitalization; (E) prolongation of hospitalization; (F) a congenital anomaly/birth defect; or (G) an important medical event that jeopardizes the Study participant and requires medical/surgical intervention to prevent one of the outcomes listed in (A) through (F) of this definition; (iii) **"Safety Information"** means any Adverse Events, Serious Adverse Events, Product Complaints and Special Situations; and (iv) "**Special Situation**" means any pregnancy exposure, overdose, abuse, off-label use, misuse, medication error, lack of efficacy or occupational exposure with the

study drug.

1.3.22: Provide information sharing strategy with the USG as well as the product Sponsor inclusive of intermediate data points.

1.3.xx: Shall prepare an interim report of the results of the Study and provide it to USG/USG representatives within one month after completing the Phase II portion of the Study. Pharm-Olam shall prepare a final report of the results of the Study and a summary of all Safety Information (as defined) that was collected during the course of the Study and provide it to USG/USG representatives within two months after completing the entire Study.

1.3.23: Provide an approach for the receipt, storage, shipment and recording of products and any other materials associated with the investigational products and the clinical trial.

1.3.xx: Shall maintain adequate records to account for the Study Product, including, without limitation, dates,
(b) (4)

(i)damaged or broken product or packaging issues
(ii) product appearance whose color/markings do not match the labeling
(iii) labeling discrepancies/inadequacies in the labeling/instructions
(iv) missing components/product
(v) any death of a patient
(vi) device not working properly or use errors
(vii) any illness, injury, or adverse event in the proximity of the device
(viii) an adverse event that could be a result of using the device
(ix) any event needing medical or surgical intervention, including hospitalization, while using the device

1.3.24: Prepare all data and documents from clinical trial in accordance with FDA or equivalent regulatory requirements and standards.

1.3.25: Establish statistical and data coordination infrastructure to provide study design and data analyses, web portal for study wide communication and document sharing/reviews, 21 CFR Part 11 validated computer systems, standards/templates, standard operating procedures and project management, harmonized clinical data standards (e.g. CDISC SDTM and Adam), Archive for study data and trial master files, data governance, transfer, integration and reporting, provide operations support.

1.3.26: Provide full scope of statistical and data management services. Providing full-scope statistical support

ranging from development of the study protocol and study related documents such as statistical analysis plan (SAP) and clinical study report (CSR). Providing, managing and supporting the safety oversight committee (DSMB), providing full scope of data management support (clinical database development and support, safety database development and support, IWRS development and support, data cleaning review, data listings, data status metrics, preparation of study related materials (including data collection forms and innovative patient report solutions (i.e. eDiary card)), instructions, training as applicable, medical and drug coding. Serious adverse event reporting, database training and assessment of site capabilities for data collection and management.

1.3.27: Provide a clinical site management and monitoring plan to ensure the conduct of the trial follows approved protocol, cGCP, cGCLP and all applicable regulatory and local requirements. Organize and provide all site training, perform protocol specific clinical site monitoring, identification, assessments and develop selection plans, perform clinical site visits (site qualification visits, site initiation visits, routine monitoring visits and site close out visits and develop and implement a robust risk based monitoring plan (including on-site and remote monitoring options) with quality metric deliverables on an ongoing basis to evaluate site status.

1.3.28: Authoring regulatory submissions (Pre-IND, original IND submission, protocol amendments, safety reports and IND annual reports). Perform quality control, publish and transmit FDA submissions (briefing documents, meeting requests, meeting package, pre-IND submissions, IND submissions, BLA application, IND annual report etc.) which are compliant with electronic CTD (eCTD) specifications and applicable regulatory requirements. Submit study documents and obtain approval and annual renewals from central IRB and as required from national and local IRB/EC in other countries as appropriate.

1.3.29: Provide plan for Quality Assurance/Quality Control (QA/QC), including ensuring all data generated meet regulatory and other required standards; and establishing, implementing and maintaining SOPs, processes for internal audits, remediation procedures, and accommodation of independent auditors and procedures for study analysis and close-out.

1.3.30: Provide plan for reliance on a centralized/singular scientific and ethical review and approval process.

1.3.31: Provide study product delivery and distribution system, provision of study supplies, oversight and monitoring and quality management system.

Key Milestone Timelines

Pharm-Olam has assumed the following milestones/deliverable based on the assumptions in the RPP. Any changes to the scope of work or delays outside the control of Pharm-Olam may change the delivery schedule below:

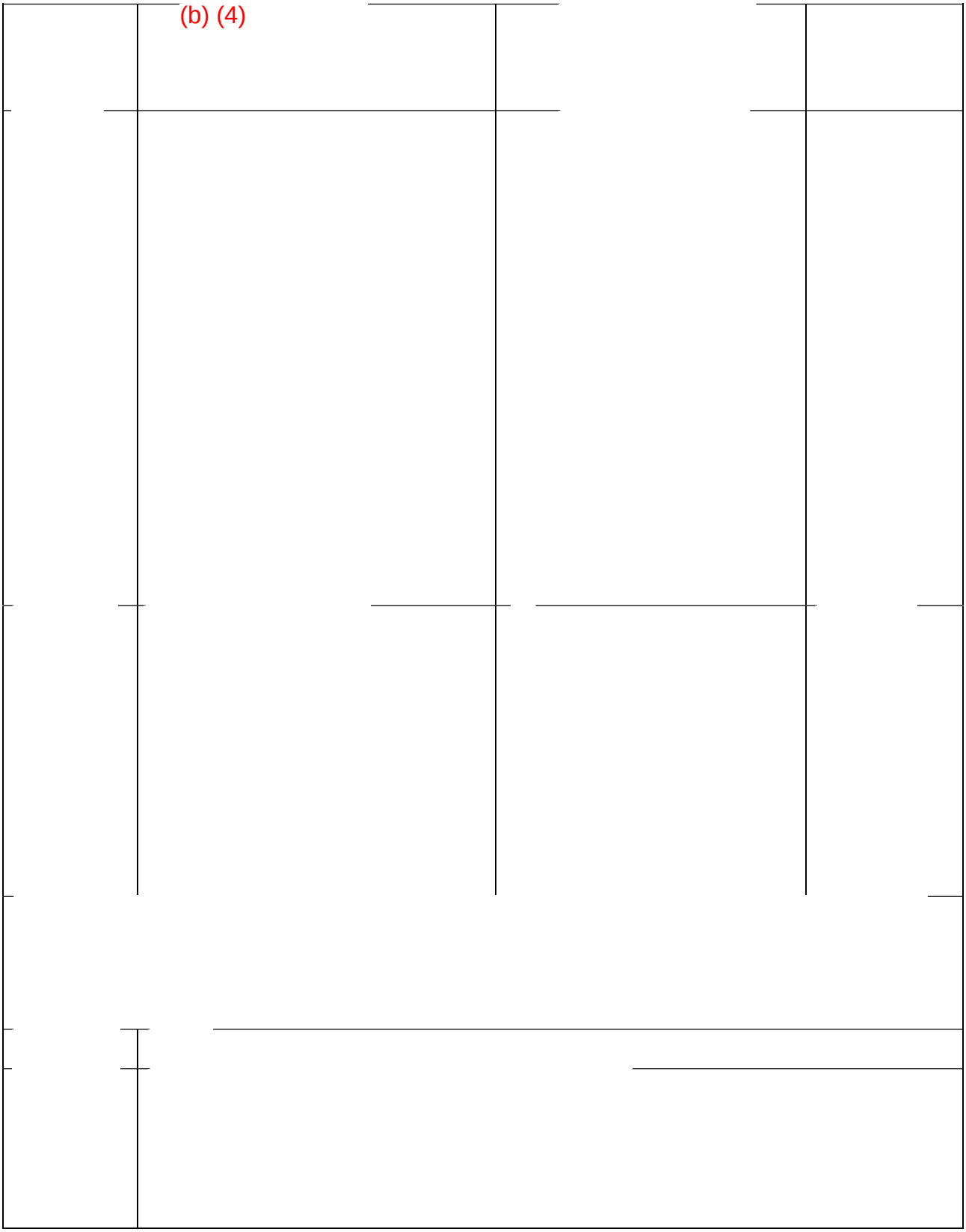
Milestone/Task	Completion/Submission Date
(b) (4)	

(b) (4)		
Total Length of Contractual Activities		**16 Months**

Study Objectives

The prospective study objectives and study design are noted below:

	Objectives	Outcome Measures	Time point(s)
Primary	(b) (4)		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Trial Participants

Patients with confirmed SARS-CoV-2 infection who are in the outpatient setting and meet the inclusion criteria.

Inclusion Criteria

Participants are eligible for the trial if all of the following are true:

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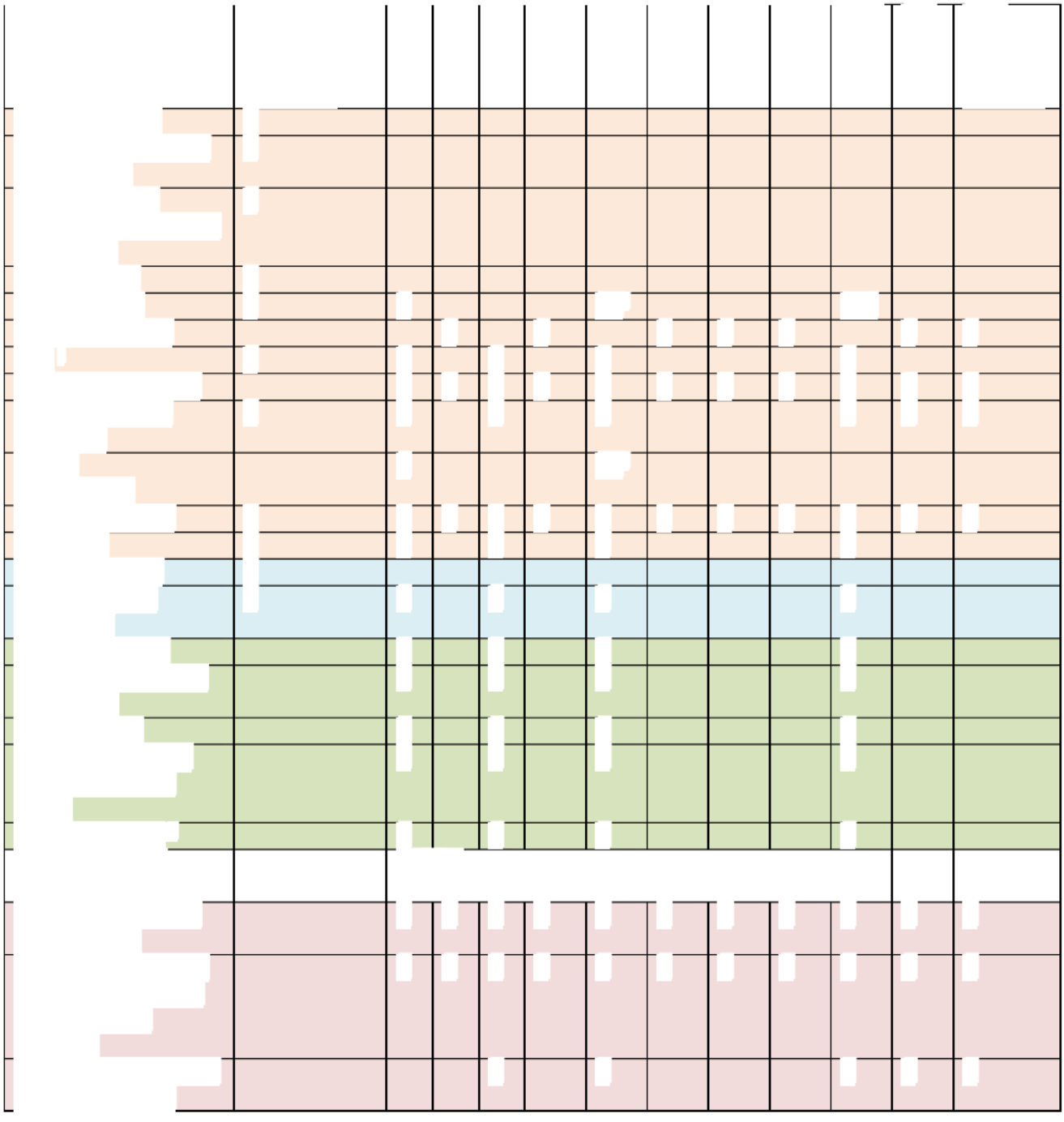
- (b) (4)

- (b) (4)



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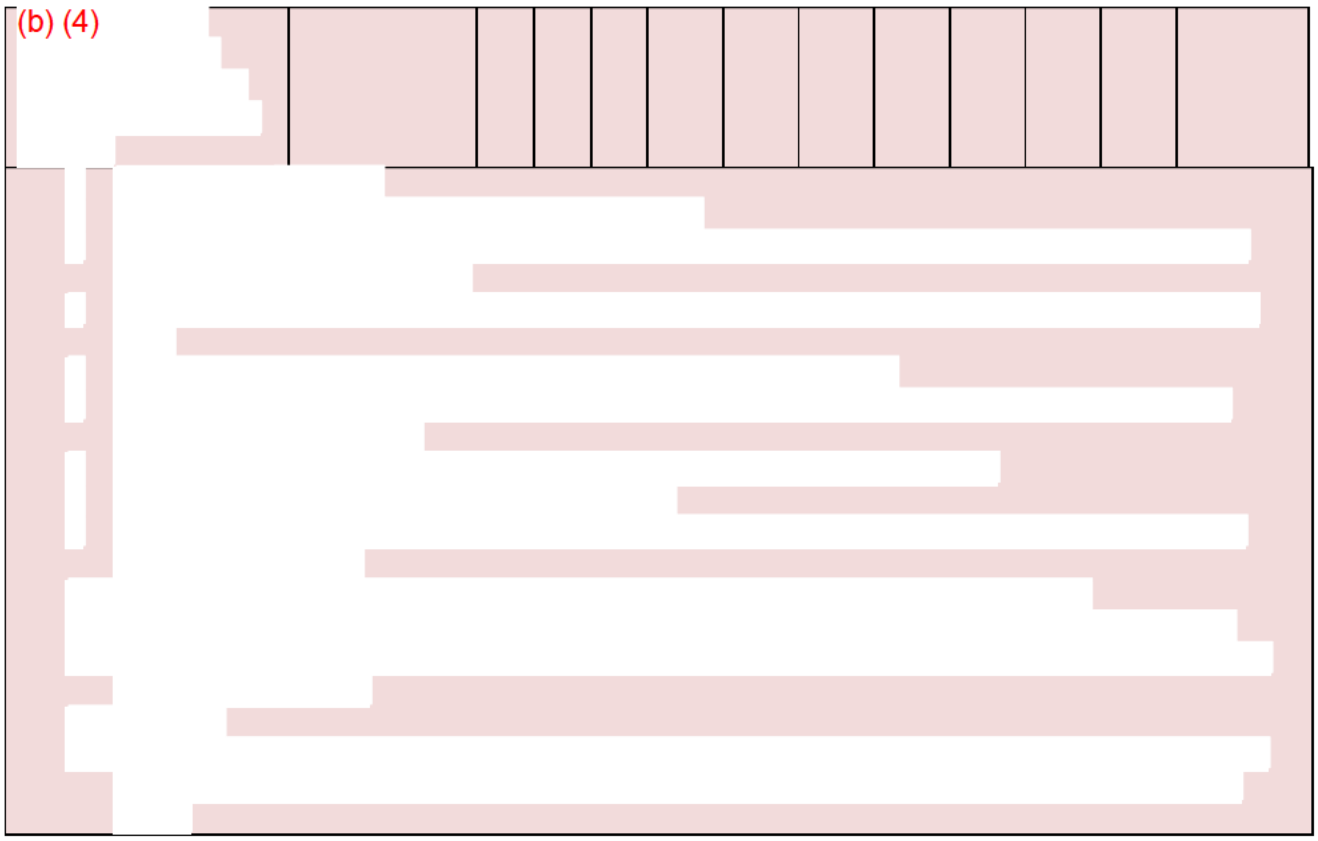

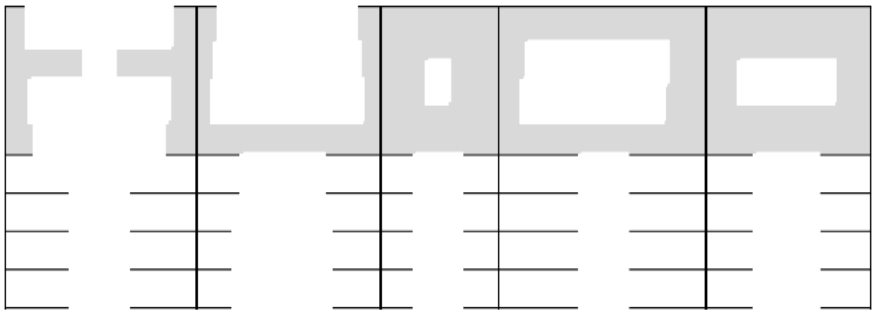

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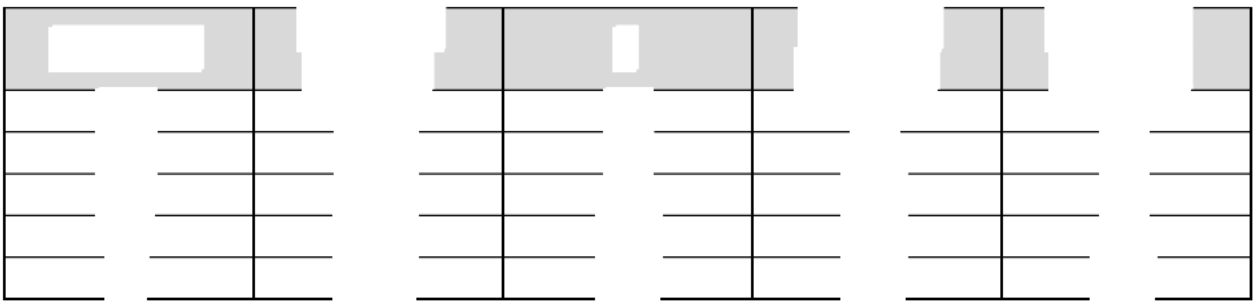

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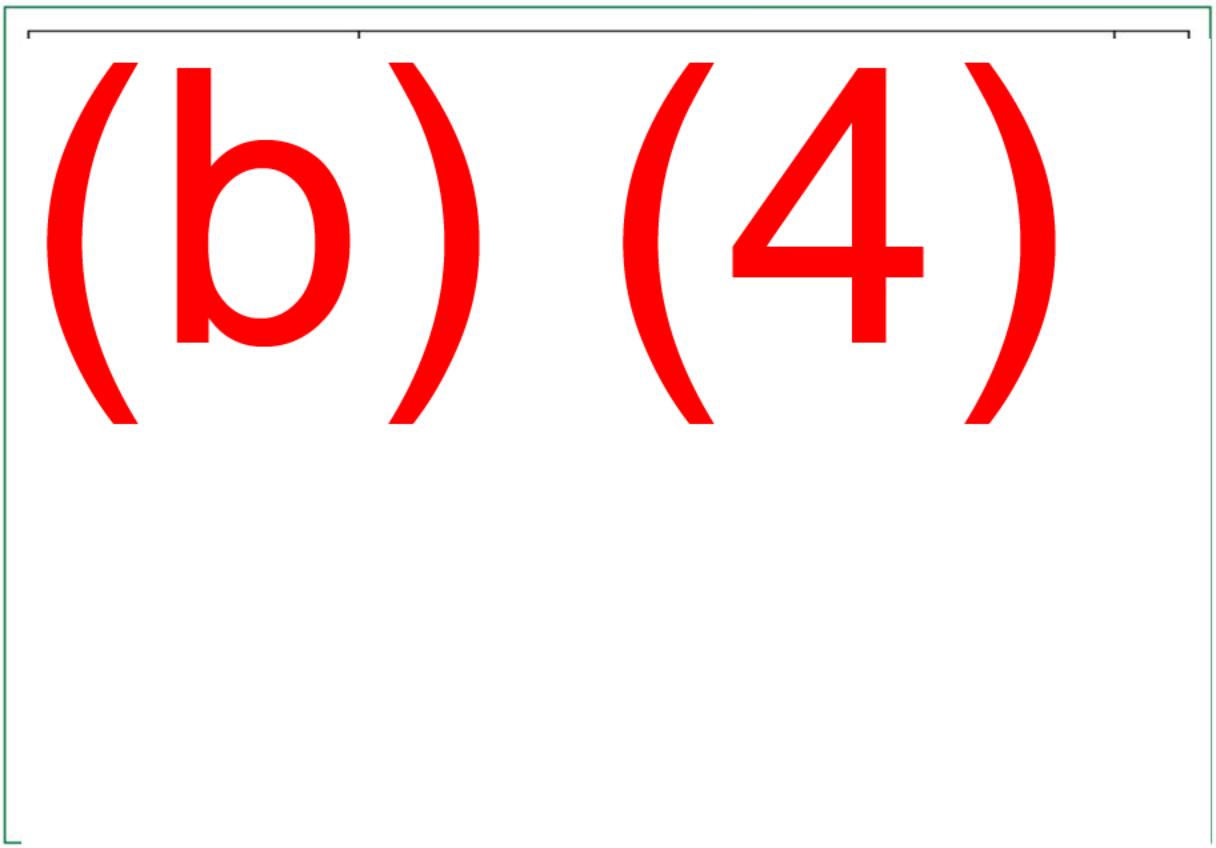

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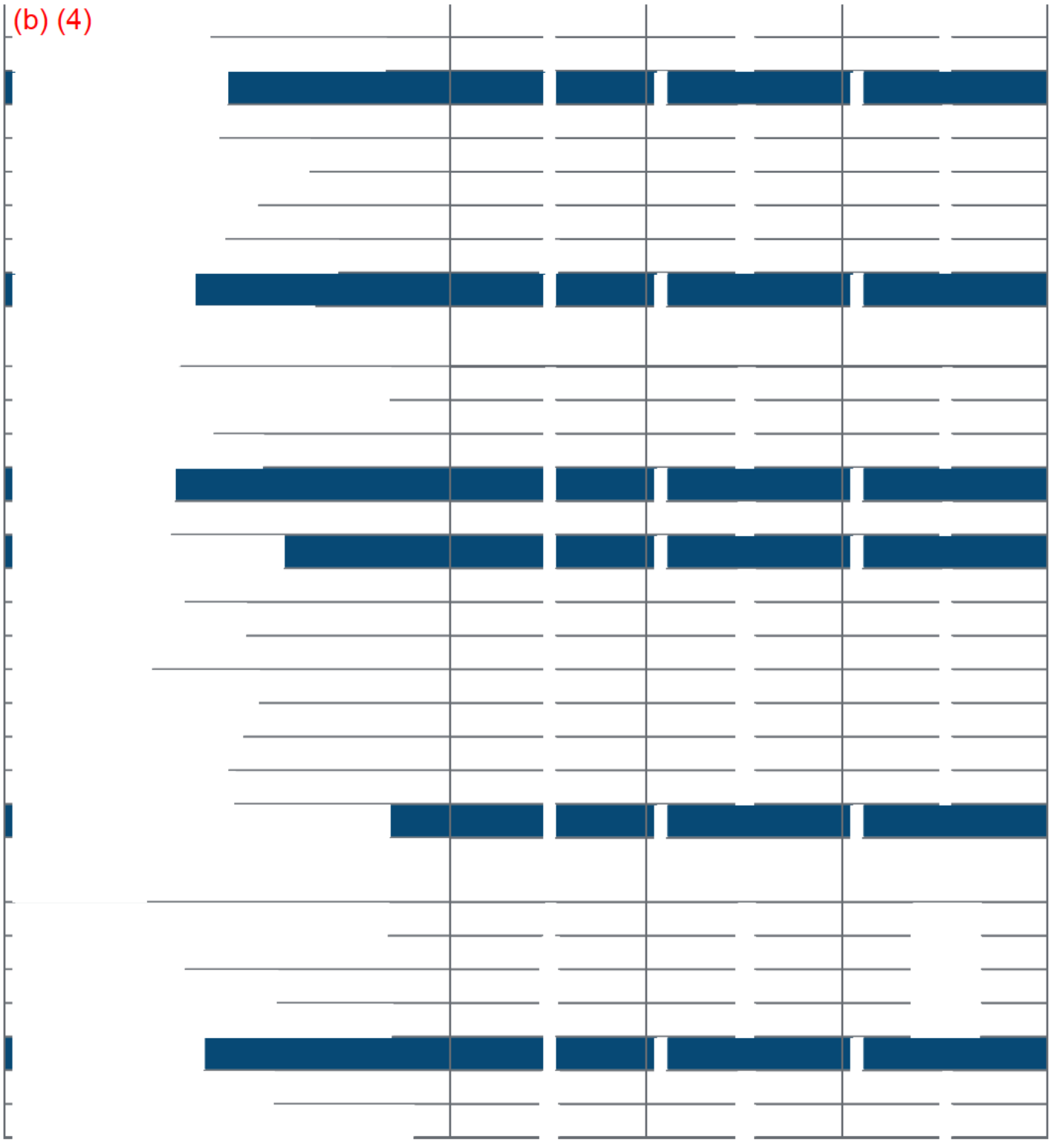

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Appendix B
Project Schedule/Milestone Payment Schedule

The Government shall pay the Awardee, upon the submission of proper invoices or vouchers, the prices stipulated in this Agreement for supplies delivered and accepted or services rendered and accepted, less any deductions provided in this Agreement. 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 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 OTAO and be in writing, of which email is an acceptable form.

The Parties acknowledge that the nature of this Prototype Project requires flexibility and the ability to react to changing circumstances. Although the Statement of Work sets the scope for activities the Government may require under this Agreement, it is not intended to, and does not, prescribe with specificity each task that Awardee will perform.

The Awardee will be responsible for submission of SOW, quotes, and proposals for cost, performance, and schedule for those efforts not already identified, priced or otherwise negotiated. Government approval will be required prior to incurring costs. In addition, subawards not already negotiated, will require Government review and determination of reasonableness.

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 OTAO and be in writing, of which email is an acceptable form.

Appendix C
Key Personnel

1. Awardee's Organization and Key Personnel.

a. The Awardee'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 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 OTAO. 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 OTAO 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. No reassignment shall be made by the Awardee without written consent of the OTAO. The "Key Personnel" list presented in Table 2 below may be amended from time to time during the course of the Agreement to either add or delete personnel, as appropriate.

Table 2: Key Personnel
Summary

(b) (6)

(b) (6)

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 under fixed price terms of this Agreement (FP-GP) if 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 OTAO who will advise the Awardee on a course of action to remedy the problem.

FPGP includes: [Mark N/A if none]:

Reference Government provided spreadsheet maintained by the Awardee and incorporated into the agreement upon approval by the OTAO.

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 OTAO, 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 OTAO.

Upon conclusion or termination of the Agreement, the Awardee shall submit a request in writing to the OTAO, 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, reasonable wear and tear or manufacturing defects. THE AWARDEE SHALL BE LIABLE FOR LOSS OF GOVERNMENT PROPERTY IN AWARDEE'S POSSESSION, EXCEPT WHEN ANY ONE OF THE FOLLOWING APPLIES: (I) OTAO GRANTS RELIEF OF RESPONSIBILITY AND LIABILITY FOR LOSS OF THE PARTICULAR GOVERNMENT PROPERTY; (II) GOVERNMENT PROPERTY IS DELIVERED OR SHIPPED UNDER THE GOVERNMENT'S INSTRUCTIONS AND SHIPPERS; OR (III) GOVERNMENT PROPERTY IS DISPOSED OF IN ACCORDANCE WITH THE GOVERNMENT'S DIRECTIONS.

APPENDIX E

EXHIBIT B

MODEL AUTHORIZATION FOR FDA TO SHARE NON-PUBLIC INFORMATION WITH THE DEPARTMENT OF DEFENSE

[To be completed on applicant/sponsor/information-owner letterhead]

[FDA Official – e.g., Center or Office Director]

United States Food and Drug Administration

10903 New Hampshire Avenue

Building __, Room ____

Silver Spring, MD 20993

[Identify relevant FDA Tracking number – e.g., NDA/ANDA/BLA, EUA/Pre-EUA, master file, etc.)]

Re: FDA Sharing of Non-Public Information Concerning [*insert name of regulated product(s)*] with Department of Defense (DoD) Partners[1]

On behalf of [*insert name of information owner*], I authorize the United States Food and Drug Administration (FDA) to share with DoD Partners, and with contractors to those Partners, all information concerning the above described product(s) that [*insert name of information owner*] has provided or will provide to FDA or to any other DoD Partner. I understand that those Partners have committed to use such information only for the purposes of the DoD and have committed or are otherwise legally required to maintain the confidentiality of such information (or both), and that contractors to DoD are bound by their contracts to maintain the confidentiality of the information. I understand that the information may contain confidential commercial or financial information or trade secrets within the meaning of 18 USC § 1905, 21 USC § 331(j), and 5 USC § 552(b)(4), that is exempt from public disclosure. I agree to hold FDA harmless for any injury caused by FDA's disclosure of this information.

Authorization is given to FDA to share this information without deleting confidential commercial or financial or trade secret information. This authorization shall remain valid unless revoked in writing. As indicated by my signature, I am authorized to provide this consent on behalf of [*insert name of information owner*] and my full name, title, address, telephone number, and facsimile number are set out below for verification.

Sincerely,

[1] DoD Partners include the U.S. Army Medical Research and Materiel Command (USAMRMC), the Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND), Joint Science and Technology Office (JSTO) of the Defense Threat Reduction Agency (DTRA), the Defense Advanced Research Projects Agency (DARPA), and other DoD entities.

(Signature)

(Printed name)

(Title)

(Address)

(Telephone & Facsimile Numbers)

cc:
Office of Counterterrorism and Emerging Threats (OCET), Office of the Chief Scientist, FDA (EUA.OCET@fda.hhs.gov)
The primary MCM Center, as follows:
For CBER, (Counterterrorism and Medical Countermeasures Staff or CBEREUA@fda.hhs.gov)
For CDER, (Counter-Terrorism and Emergency Coordination Staff or CDEREUA@fda.hhs.gov)
For CDRH, for IVD medical devices, (device@fda.hhs.gov) and for non-IVD medical devices (cdrhemcm@fda.hhs.gov)