

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT			1. CONTRACT ID CODE	PAGE OF PAGES	
2. AMENDMENT/MODIFICATION NO. P00002		3. EFFECTIVE DATE 10-Jun-2021	4. REQUISITION/PURCHASE REQ. NO. 0011546770		5. PROJECT NO.(If applicable) 1 2
6. ISSUED BY US ARMY ACC-APG-RTP W911NF 800 PARK OFFICE DRIVE SUITE 4229 RESEARCH TRIANGLE PARK NC 27709		CODE W911NF	7. ADMINISTERED BY (If other than item 6) DCMA BOSTON 37 GRENIER ST. BLDG. 1108 HANSCOM AFB MA 01731		CODE S2206A SCD: C
8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code) GLOBAL LIFE SCIENCES SOLUTIONS USA LLC 100 RESULTS WAY MARLBOROUGH MA 01752-3078			9A. AMENDMENT OF SOLICITATION NO.		
			9B. DATED (SEE ITEM 11)		
			X 10A. MOD. OF CONTRACT/ORDER NO. W911NF2130001		
			X 10B. DATED (SEE ITEM 13) 13-Oct-2020		
CODE 00JRI		FACILITY CODE			
11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS					
<input type="checkbox"/> The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer <input type="checkbox"/> is extended, <input type="checkbox"/> is not extended.					
<p>Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods:</p> <p>(a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.</p>					
12. ACCOUNTING AND APPROPRIATION DATA (If required)					
13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACT ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.					
A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.					
X B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).					
C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:					
D. OTHER (Specify type of modification and authority)					
E. IMPORTANT: Contractor <input checked="" type="checkbox"/> is not, <input type="checkbox"/> is required to sign this document and return _____ copies to the issuing office.					
14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.) Modification Control Number: (b) (6) The purpose of this modification is to transfer Purchasing Office responsibility FROM W911NF (ACC-APG RTP Division) TO W58F05 (ACC-APG COVID Response Division). All other terms and conditions remain unchanged and in full force and effect.					
Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.					
15A. NAME AND TITLE OF SIGNER (Type or print)			16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) (b) (6) / CONTRACTING OFFICER		
			TEL: (b) (6) EMAIL: (b) (6)		
15B. CONTRACTOR/OFFEROR (Signature of person authorized to sign)		15C. DATE SIGNED	16B. UNITED STATES OF AMERICA B (b) (6) (Signature of Contracting Officer)		16C. DATE SIGNED 10-Jun-2021

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

(End of Summary of Changes)

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT			1 CONTRACT ID CODE	PAGE OF PAGES 1 3
2 AMENDMENT/MODIFICATION NO P00001	3 EFFECTIVE DATE 17-Nov-2020	4 REQUISITION/PURCHASE REQ NO 0011546770	5 PROJECT NO (If applicable)	
6 ISSUED BY US ARMY ACC-APG-RTP W911NF 800 PARK OFFICE DRIVE SUITE 4229 RESEARCH TRIANGLE PARK NC 27709	CODE W911NF	7 ADMINISTERED BY (If other than item 6) DCMA BOSTON 37 GRENER ST. BLDG. 1108 HANSCOM AFB MA 01731	CODE S2206A	SCD: C
8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code) GLOBAL DEFENSE SOLUTIONS USA LLC 100 RESULTS WAY MARLBOROUGH MA 01752-3078			9A. AMENDMENT OF SOLICITATION NO.	
			9B. DATED (SEE ITEM 11)	
			X 10A. MOD. OF CONTRACT/ORDER NO. W911NF2130001	
			X 10B. DATED (SEE ITEM 13) 13-Oct-2020	
CODE 00JR1	FACILITY CODE			
11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS				
<input type="checkbox"/> The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of offer <input type="checkbox"/> is extended, <input type="checkbox"/> is not extended.				
<p>Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods:</p> <p>(a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.</p>				
12. ACCOUNTING AND APPROPRIATION DATA (If required)				
13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACT ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.				
A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.				
B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).				
C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:				
X D. OTHER (Specify type of modification and authority) Unilateral; Add DPAS Rating IAW approval 10 dated November 2020				
E. IMPORTANT: Contractor <input checked="" type="checkbox"/> is not, <input type="checkbox"/> is required to sign this document and return _____ copies to the issuing office.				
14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.) Modification Control Number: creechw21331 COVID-19: The purpose of this modification is to add Defense Priorities Allocation System (DPAS) rating DO-C9 to this effort. SEE CONTINUATION PAGE(S).				
Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect				
15A. NAME AND TITLE OF SIGNER (Type or print)			16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) (b) (6) / CONTRACT NG/GRANTS OFFICER TEL: (b) (6) EMAIL: (b) (6)	
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA BY (b) (6)	16C. DATE SIGNED 17-Nov-2020	
(Signature of person authorized to sign)		(Signature of Contracting Officer)		

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION SF 30 - BLOCK 14 CONTINUATION PAGE

The following have been added by full text:

This documents constitutes modification P00001 to Technology Investment Agreement (TIA) W911NF2130001 with Global Life Sciences Solutions USA, LLC.

1. A DPAS Rating of DO-C9 is hereby added in accordance with the approval dated 10 November 2020.

This is a rated order certified for national defense and emergency preparedness and the Recipient shall follow all the requirements of the Defense Priorities and Allocations System regulation (15 CFR 700).

a. Elements of a rated order are as follows:

- i. Appropriate Priority Rating and Program Identification Symbol: **DO-C9**
- ii. Required Delivery Dates/Period of Performance: **13 October 2020 – (b) (4)**
- iii. Written Signature: **provided in the original agreement**
- iv. Statement: **This is a rate order certified for national defense use and you are required to follow all provisions of the Defense priorities and Allocations Systems Regulations (15 CFR 700).**
- v. Additional element for emergency preparedness: **This rated order is placed for the purpose of emergency preparedness. It must be accepted or rejected within 15 working day of receipt of order. This language shall flow down to subawards for industrial resource-services only.**

2. As a result of adding the DPAS rating in #1 above, FAR 52.211-15, Defense Priority and Allocation Requirements is hereby incorporated by reference.

3. All other terms and conditions remain unchanged and in full force and effect.

The following have been deleted:

SECTION A - SOLICITATION/CONTRACT FORM

The DPAS code DO-C9 has been added.

SECTION I - CONTRACT CLAUSES

The following have been added by reference:

52.211-15

Defense Priority And Allocation Requirements

APR 2008

(End of Summary of Changes)

AWARD/CONTRACT		1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)			RATING	PAGE OF PAGES 1 36	
2. CONTRACT (Proc. Inst. Ident.) NO. W911NF2130001		3. EFFECTIVE DATE 13 Oct 2020		4. REQUISITION/PURCHASE REQUEST/PROJECT NO. 0011546770			
5. ISSUED BY US ARMY ACC-APG-RTP W911NF 800 PARK OFFICE DRIVE SUITE 4229 RESEARCH TRIANGLE PARK NC 27709		CODE W911NF	6. ADMINISTERED BY (If other than Item 5) DCMA BOSTON 37 GRENIER ST. BLDG. 1108 HANSCOM AFB MA 01731		CODE S2206A	SCD: C	
7. NAME AND ADDRESS OF CONTRACTOR (No., street, city, county, state and zip code) GLOBAL LIFE SCIENCES SOLUTIONS USA LLC 100 RESULTS WAY MARLBOROUGH MA 01752-3078				8. DELIVERY [] FOB ORIGIN [X] OTHER (See below)		9. DISCOUNT FOR PROMPT PAYMENT Net 30 Days	
CODE 00JR1				FACILITY CODE		10. SUBMIT INVOICES 1 ITEM (4 copies unless otherwise specified) TO THE ADDRESS SHOWN IN: Block 6	
11. SHIP TO/MARK FOR JPM MEDICAL MEDICAL COUNTERMEASURE SYSTEMS 1564 FREEDMAN DRIVE FORT DETRICK, MD MD 21702		CODE W56XNH	12. PAYMENT WILL BE MADE BY DFAS COLUMB-NORTH ENTITLEMENT OPERATIONS P.O. BOX 182266 COLUMBUS OH 43218-2266		CODE HQ0337		
13. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION: [] 10 U.S.C. 2304(c)() [] 41 U.S.C. 253(c)()			14. ACCOUNTING AND APPROPRIATION DATA See Schedule				
15A. ITEM NO.	15B. SUPPLIES/ SERVICES		15C. QUANTITY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT	
SEE SCHEDULE							
15G. TOTAL AMOUNT OF CONTRACT						\$32,190,000.00	
16. TABLE OF CONTENTS							
(X)	SEC.	DESCRIPTION	PAGE(S)	(X)	SEC.	DESCRIPTION	PAGE(S)
PART I - THE SCHEDULE				PART II - CONTRACT CLAUSES			
X	A	SOLICITATION/ CONTRACT FORM	1 - 31	I	CONTRACT CLAUSES		
X	B	SUPPLIES OR SERVICES AND PRICES/ COSTS	32 - 34	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			
	E	INSPECTION AND ACCEPTANCE		K	REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS		
X	F	DELIVERIES OR PERFORMANCE	35	L	INSTRS., CONDS., AND NOTICES TO OFFERORS		
X	G	CONTRACT ADMINISTRATION DATA	36	M	EVALUATION FACTORS FOR AWARD		
	H	SPECIAL CONTRACT REQUIREMENTS					
CONTRACTING OFFICER WILL COMPLETE ITEM 17 (SEALED-BID OR NEGOTIATED PROCUREMENT) OR 18 (SEALED-BID PROCUREMENT) AS APPLICABLE							
17. [X] CONTRACTOR'S NEGOTIATED AGREEMENT (Contractor is required to sign this document and return 1 copies to issuing office.) Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any continuation sheets for the consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the following documents: (a) this award/contract, (b) the solicitation, if any, and (c) such provisions, representations, certifications, and specifications, as are attached or incorporated by reference herein. (Attachments are listed herein.)				18. [] SEALED-BID AWARD (Contractor is not required to sign this document.) Your bid on Solicitation Number _____ including the additions or changes made by you which additions or changes are set forth in full above, is hereby accepted as to the 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) (b) (6) - Vice President Global Supply Chain				20A. NAME OF CONTRACTING OFFICER (b) (6) TEL: (b) (6) EMAIL: (b) (6)			
19B. NAME OF CONTRACTOR (b) (6)		19C. DATE SIGNED 12 Oct 20		20B. UNITED STATES OF AMERICA (b) (6)		20C. DATE SIGNED 13 Oct 2020	
BY (b) (6)				BY _____ (Signature of Contracting Officer)			

AWARD/CONTRACT		1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)			RATING		PAGE OF PAGES 1 36			
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					9. DISCOUNT FOR PROMPT PAYMENT Net 30 Days					
					10. SUBMIT INVOICES 1 (4 copies unless otherwise specified) TO THE ADDRESS SHOWN IN:		ITEM Block 6			
CODE 00JR1		FACILITY CODE								
11. SHIP TO/MARK FOR JPM MEDICAL MEDICAL COUNTERMEASURE SYSTEMS 1564 FREEDMAN DRIVE FORT DETRICK, MD MD 21702		CODE W56XNH	12. PAYMENT WILL BE MADE BY DFAS COLUMB-NORTH ENTITLEMENT OPERATIONS P.O. BOX 182266 COLUMBUS OH 43218-2266			CODE HQ0337				
13. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION: [] 10 U.S.C. 2304(c)() [] 41 U.S.C. 253(c)()				14. ACCOUNTING AND APPROPRIATION DATA See Schedule						
15A. ITEM NO.	15B. SUPPLIES/ SERVICES		15C. QUANTITY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT				
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15G. TOTAL AMOUNT OF CONTRACT								\$32,190,000.00		
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	C	DESCRIPTION/ SPECS/ WORK STATEMENT				J	LIST OF ATTACHMENT			
	D	PACKAGING AND MARKING				PART IV - REPRESENTATIONS AND INSTRUCTIONS				
	E	INSPECTION AND ACCEPTANCE				K	REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS			
X	F	DELIVERIES OR PERFORMANCE			35	L	INSTRS., CONDS. AND NOTICES TO OFFERORS			
X	G	CONTRACT ADMINISTRATION DATA			36	M	EVALUATION FACTORS FOR AWARD			
	H	SPECIAL CONTRACT REQUIREMENTS								
CONTRACTING OFFICER WILL COMPLETE ITEM 17 (SEALED-BID OR NEGOTIATED PROCUREMENT) OR 18 (SEALED-BID PROCUREMENT) AS APPLICABLE										
17. [X] CONTRACTOR'S NEGOTIATED AGREEMENT (Contractor is required to sign this document and return 1 copies to issuing office.) Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any continuation sheets for the consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the following documents: (a) this award/contract, (b) the solicitation, if any, and (c) such provisions, representations, certifications, and specifications, as are attached or incorporated by reference herein. <u>(Attachments are listed herein.)</u>					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) TEL: (b) (6) EMAIL: (b) (6)					
19B. NAME OF CONTRACTOR BY _____ (Signature of person authorized to sign)			19C. DATE SIGNED		20B. UNITED STATES OF AMERICA (b) (6) BY _____ (Signature of Contracting Officer)			20C. DATE SIGNED 13-Oct-2020		

Section SF 30 - BLOCK 14 CONTINUATION PAGE

Technology Investment Agreement
Between
Global Life Sciences Solutions USA LLC
And
Department of Defense
US Army Contracting Command – Aberdeen Proving Ground
Research Triangle Park Division
(ACC-APG-RTP)
on behalf of
Biomedical Advanced Research and Development Authority (BARDA)
for the Project:
Capacity Expansion for COVID-19 Response and in support of Public Health Emergencies

Agreement No: W911NF-21-3-0001

Total Amount Obligated by Government under the Agreement: \$32,190,000

Total Cost Share for the Agreement: \$33,503,000

Total Estimated Value of the Agreement: \$65,693,000

Period of Performance: (b) (4)

Authority: 10 U.S.C. 2358 and 10 U.S.C. 2371

CFDA No.: 12.360

Technology Investment Agreement Terms and Conditions

Articles

Scope of Agreement
Term of Agreement
Order of Precedence
Program/Administrative Management
Financial Management & Payment
Accounting & Audit
Purchasing & Title
Cost Sharing
Government Preference
Records Retention & Government Access
Intellectual Property & Patent Rights
Data Rights
FDA Regulatory Requirements
Termination
Disputes
Reports & Distribution
Modification
Miscellaneous

Attachments

Government Collaboration Plan
Advance Agreement
Additional Reporting Requirement Information
Additional Security Requirements
MCM Partner List

RECITALS

This Agreement is entered into between the United States of America, Department of Defense, represented by ACC-APG-RTP (“Government”) and Global Life Sciences Solutions USA LLC (“Recipient”), collectively referred to as the “Parties,” pursuant to and under the statutory authority at 10 U.S.C. §2371 and/or 10 U.S.C. §2358.

The Recipient, a for-profit firm, submitted a basic, applied, or advanced research or development proposal to the Government in response to the publicly disseminated Medical Countermeasures System (MCS) Broad Agency Announcement (BAA) 17-01. The proposal was identified within the MCS BAA scope of: Advanced Development & Manufacturing Capabilities (ADMC), to develop a national capability and capacity to develop and produce medical countermeasures rapidly to counter known or unknown chemical, biological, radioactive, and nuclear (CBRN) threats, including novel and previously unrecognized, naturally- occurring emerging infectious diseases such as the COVID-19 virus. The specific MSC BAA Area of Interest is Medical Chemical Biological Countermeasures.

The Government awards this Technology Investment Agreement (TIA) to fund the Recipient proposal subject to the following terms and conditions and other statutory requirements. The Parties desire to enter into this Agreement to establish said terms and conditions under which they plan to carry out the activities as described below.

THEREFORE, THE PARTIES AGREE:

1. Scope of Agreement

1.1 Governing Authority

This Technology Investment Agreement (TIA) is an assistance transaction other than a grant or cooperative agreement and is awarded pursuant to 10 USC §2371 and/or 10 USC §2358, as applicable, as implemented by 32 Code of Federal Regulations (CFR) Part 37, and Parts 22 and 34 where specifically referenced. The following are also incorporated in full, to the extent applicable: Definitions at Subpart J of 32 CFR Part 37; National Policies at Appendix B, 32 CFR Part 22 to the extent referenced in Appendix D, 32 CFR Part 37; Audits at Appendix C of 32 CFR Part 37. This TIA is subject to good manufacturing practices (GMPS) at 21 CFR 210 and 211, as applicable. The Federal Acquisition Regulation (FAR), Defense Federal Acquisition Regulation Supplement (DFARS), DoD Grant and Agreement Regulations (DoDGARs), or other regulatory and statutory requirements apply only as specifically referenced herein. If this instrument is awarded under 10 USC §2358, then the Bayh-Dole Act, 35 U.S.C. §200-212 also applies, if applicable.

1.2 Principal Purpose

The Government and the Recipient agree that the principal purpose of this Agreement is for Government investment into the expansion of Recipient’s existing capacities to support efforts in pursuit of domestic development and distribution of a vaccine in response to the worldwide COVID-19 pandemic, and any future PHE (defined below), and to utilize that expanded capacity for the term (defined below) to manufacture, produce, and sell single use consumables and hardware (b) (4) as described in section 9.2 (b) (4). This Agreement is not intended to be, nor shall it be construed as, by implication or otherwise, a partnership, a corporation, or other business organization.

2. Term of Agreement

This Agreement shall commence upon the effective date listed on page 1, after execution of the Agreement by both parties, until (b) (4), the “term” of the Agreement or “Period of Performance.” *Period of performance* means the time during which a Recipient or Subrecipient may incur new obligations to carry out the work authorized under an award or subaward, respectively, provided that no obligations shall continue beyond the end of any optional availability period that is exercised by the Government. The Government shall have the right to extend the

term of the Agreement for (b) (4) optional availability periods with the final such option period, if exercised, thereby extending the term of the Agreement to end (b) (4), each option exercisable no later than thirty (30) days before the expiration of the then-current term.

“PHE” means the Public Health Emergency relating to the Presidential Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak issued on 13 March 2020 or other such presidential declarations issued thereafter recognizing either (i) the continuation of the COVID-19 Public Health Emergency or (ii) any new Public Health Emergency declared by Presidential Proclamation.

3. Order of Precedence

This Agreement is subject to the laws and regulations of the United States. In the event of a conflict or inconsistency in the terms and conditions or attachments specified in this Agreement, the conflict or inconsistency shall be resolved according to the following order of precedence: (a) the Federal statute authorizing this award, including attachments where applicable; (b) Federal regulations specifically referenced; (c) the terms and conditions contained within the Agreement, including any documents incorporated; and (d) programmatic requirements.

4. Program/Administrative Management

4.1 Program Management

The Recipient has full responsibility for the Project supported by this Agreement, in accordance with the Recipient’s proposal and proposal revisions/appendices, and the terms and conditions specified in this Agreement. The Government will have continuous and/or substantial involvement with the Recipient pursuant to a Collaboration Plan that will be finalized within 30 days after award. The Recipient must consult the Program Office/Technical Representative through the Agreements Officer before deviating from the objectives or overall program of the Project originally proposed. Uncured material non-compliance with any provision of this Agreement may result in the withholding of funds and or the termination of the award.

4.2 Government Representatives

Agreements Officer

(b) (6)
ACC-APG-RTP Division
800 Park Offices Drive
Durham, NC 27703 (b) (6)
(b) (6)

Administrative Agreements Officer

(b) (6)
Defense Contract Management Agency (DCMA)
DCMA Boston
37 Griner Street, BUILDING 1108
HANSCOM AFB, MA 01731
(b) (6)
(b) (6)

BARDA Program Manager

(b) (6)
Biomedical Advanced Research and Development Authority
Department of Health and Human Services

Washington, DC

(b) (6)

4.3 Recipient's Representatives

(b) (6)

Global Program Manager
1402 Stanford Circle
Carpentersville, IL 60110

(b) (6)

5. Financial Management & Payment

5.1 Expenditure-Based

This Agreement is an expenditure type Technology Investment Agreement (TIA) as described in 32 CFR §37.1285. *Expenditure* is defined in 32 CFR §37.1290. The charges may be reported on a cash or accrual basis, as long as the methodology is disclosed and is consistently applied. In accordance with 32 CFR 37.300(a): "For an expenditure-based TIA, the amounts of interim payments or the total amount ultimately paid to the Recipient are based on the amounts the Recipient expends on project costs. If a Recipient completes the project specified at the time of award before it expends all of the agreed-upon Federal funding and Recipient cost sharing, the Federal Government may recover its share of the unexpended balance of funds or, by mutual agreement with the Recipient, amend the agreement to expand the scope of the research project. An expenditure-based TIA therefore is analogous to a cost-type procurement contract or grant." As set forth in the Advance Agreement attached as Attachment (b) (4)

consistent with the provisions of this Agreement.

5.2 Obligation

In no case shall the Government's financial obligation exceed the amount obligated on this Agreement or by amendment to the Agreement. The Government is not obligated to reimburse the Recipient for expenditures in excess of the amount of obligated funds allotted by the Government.

5.3 Wide Area Workflow. The following guidance is provided for invoicing processed under this Agreement through WAWF:

5.3.1. Acceptance within the WAWF system shall be performed by the Agreements Officer upon receipt of a confirmation email, or other form of transmittal, from the BARDA PM.

5.3.2. The Recipient shall send an email notice to the BARDA PM and upload the BARDA PM approval as an attachment upon submission of an invoice in WAWF (this can be done from within WAWF).

5.3.3. Payments shall be made by the Defense Finance and Accounting Services (DFAS) office indicated below within thirty (30) calendar days of an accepted invoice in WAWF:

Defense Finance and Accounting Service (DFAS)
DFAS COLUMBUS- North Entitlement Operations
1-800-756-4571

5.3.4. WAWF Provision:

(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 Work Flow (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 Recipient shall (i) have a designated electronic business point of contact in the System for Award Management at <https://www.acquisition.gov>; and (ii) be registered to use WAWF at <https://wawf.eb.mil/> following the step-by-step procedures for self registration available at this website.

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

(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 Recipient must use the following information when submitting payment requests and receiving reports in WAWF for this contract/order:

(1) Document type. The Recipient shall use the following document type:

Non-Procurement Instruments (NPI) Voucher

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

Routing Data Table

Pay Official DoDAAC	HQ0337
Issue By DoDAAC	W911NF
Admin DoDAAC	S2206A
Inspect By DoDAAC	W911NF
Ship To Code	W911NF
Ship From Code	N/A
Mark For Code	N/A
Service Approver DoDAAC	S2206A
Service Acceptor DoDAAC	W911NF
Accept at Other DoDAAC	N/A
LPO DoDAAC	N/A
DCAA Auditor DoDAAC	N/A
Other DoDAAC(s)	N/A

(4) Payment request and supporting documentation. The Recipient shall ensure a payment request includes appropriate contract line item and subline item descriptions of the work performed or supplies delivered, unit

price/cost per unit, fee (if applicable), and all relevant back-up documentation in support of each payment request.

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

(b) (6)

(g) WAWF point of contact.

(1) The Recipient 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

6. Accounting & Audit

6.1 Accounting System

6.1.1. The Recipient's systems must demonstrate effective control of all funds. Control systems must be adequate to ensure that costs charged to Federal funds and those counted as the Recipient's cost share or match are consistent with requirements for cost reasonableness, allowability, and allocability as set forth in 32 CFR §37.625(b) and in the terms and conditions of the award. The Recipient must be able to provide accurate, current and complete records that document for work funded wholly or in part with Federal funds the source and application of the Federal funds and the Recipient has required cost share or match.

6.1.2. The Recipient's cost accounting system shall be in compliance with Generally Accepted Accounting Principles (GAAP) in accordance with 32 CFR §37.615. The system must effectively control all Project funds, including Federal funds and any required cost share. The system must have complete, accurate, and current records that document the sources of funds and the purposes for which they are disbursed. It also must have procedures for ensuring that Project funds are used only for purposes permitted by the agreement (§ 37.625).

6.1.3. Program income derived during the initial Period of Performance from Government funding shall be allocated to finance the non-Federal share of the Project (including the amounts described in Section 8.1) in accordance with 32 CFR §34.14(d)(2). Pursuant to 32 CFR §34.14(c) costs incident to the generation of program income may be deducted from gross income to determine program income, provided these costs have not been charged to the award. As contemplated by 32 CFR §34.14(b)(2), Recipient will have no obligation to the Government for program income generated after the end of the Period of Performance, and no recovery of funds is contemplated under 32 CFR §37.580.

6.2 Annual Audit Requirement

The Recipient shall have an annual audit performed by an independent auditor, in accordance with 32 CFR §37.650. The Recipient shall provide a copy of the auditor's report to the Agreements Officer within 60 days after audit. Audits at Appendix C of 32 CFR Part 37 is incorporated into this Agreement. For the avoidance of doubt, and due to the Recipient's Labor and G&A Rates having been agreed upon between the Recipient and the Government prior to Agreement award, the annual audits shall not include a review of the calculation of such rates.

7. Purchasing & Title

(b) (4)

[REDACTED]

7.2 Purchasing System. Recipient may use its existing purchasing systems, as long as applicable requirements are flowed down (37.705).

8. Cost Sharing

8.1 The Recipient has demonstrated a strong commitment to and self-interest in the success of the Project, as evidenced by its initial planning for this project (early 2020) and commitment to cover [REDACTED] % of the project costs [REDACTED] which will include (b) (4) [REDACTED] identified in its proposal. Accordingly, the Government has evaluated and determined that Recipient's investment has satisfied the cost share requirements set out in 32 CFR § 37.215.

9. Government Preference

9.1 (b) (4) [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

9.2 (b) (4) [REDACTED]

(b) (4) [Redacted text block]

(b) (4) [Large redacted text block]

9.3 (b) (4) (b) (4) [Redacted text block]

10. Records Retention & Government Access

The DoD, Comptroller General of the United States, or any of their duly authorized representatives, have the right of timely and unrestricted access to any books, documents, papers, or other records of the Recipient that are pertinent solely to the Recipient's technical performance under this Agreement, in order to make examinations, excerpts, transcripts and copies of such documents; provided that all information disclosed shall be deemed to be and marked as the commercial confidential information of Recipient. This right also includes timely and reasonable access to the Recipient's personnel for the purpose of interview and discussion related to such records.

Such access shall be performed during business hours on business days upon written notice and shall be subject to the security requirements of the audited Party to the extent such security requirements do not conflict with the rights of access otherwise granted by this paragraph. The rights of access in this paragraph shall last as long as records are retained. The rights of access in this paragraph do not extend to the Recipient's financial records or any of its affiliates, segments, or subsidiaries.

11. Intellectual Property & Patent Rights

11.1 Background IP and Materials. The Recipient 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).

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

11.3 Ownership. Ownership of any invention, regardless of whether it is not patentable, held as a trade secret or is patentable under U.S. patent law that is conceived or first reduced to practice under this Agreement (an “Invention”) will follow inventorship in accordance with U.S. patent law. The Parties represent and warrant that each inventor will assign his or her rights in any such Inventions to his or her employing organization.

11.4 Patent Applications. Irrespective of any Disclosure of Information clauses in this Agreement the Parties will respectively have the option to file a patent application claiming any 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 Invention. Within two months of being notified of the discovery of an Invention or filing a patent application covering an 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 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.

11.5 Licenses. Upon the Recipient’s request, the Government agrees to enter into good faith negotiations regarding the Recipient’s receipt of a nonexclusive commercialization license covering the Government’s interest in any Invention made in whole or in part by a Government employee. Any Invention made by a Recipient employee is subject to the provisions of the Bayh-Dole Act.

11.6 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.

12. Data Rights

12.1 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 Recipient in the performance of this Agreement, other materials or confidential information, whether conducted by the Government or the Recipient shall be owned by the Recipient. As a result of this Agreement, the Government shall obtain “Limited rights,” as this term is defined in DFARS 252.227-7013(a)(14) in any data generated under this Agreement.

12.2 Marking of Data: The Recipient is responsible for affixing appropriate markings indicating the rights of the Recipient on all data and technical data delivered under this Agreement. Any rights that a Party may have in data delivered under this Agreement, whether arising under this Agreement or otherwise, will not be affected by a Party’s failure to mark data pursuant to this Article. Any distribution markings shall be established by the GPM and incorporated prior to distribution.

12.3 Any Software (as that term is defined in DFARS 252.227-7014) developed under this Agreement shall be owned by the Recipient subject to “Restricted Rights” (as that term is defined in DFARS 252.227-7014(a)(15)) held by the Government, noting that no Software is expected to be developed under this Agreement. The Recipient shall deliver source and object code for each instance of Software developed under the Agreement in accordance with the requirements of the other deliverables under this Agreement. Use of any open source code in any Software required to be delivered to the Government shall be subject to approval of the Government.

13. FDA Regulatory Compliance

13.1 GMP Compliance. To the extent required under the Federal Food, Drug, and Cosmetic Act (FFDCA), the Recipient will ensure that the manufacturing capability established under this Agreement complies with current good manufacturing practices (cGMPs) under 21 CFR 210 and 211. The Recipient will notify the Government of any written cGMP inspection findings from the U.S. Food and Drug Administration (FDA) pertinent to the manufacturing capability established under this Agreement. Notwithstanding the foregoing, the Government acknowledges that the FFDCA does not require Recipient to manufacture its products to cGMP.

13.2 FDA Communications. The Recipient will provide the Government with summaries of any Recipient formal meetings with the FDA and future correspondence between Recipient and the FDA regarding the manufacturing contemplated under this Agreement and ensure that Government representatives are invited to participate in any Recipient formal meetings with the FDA regarding topics that are material to Recipient's compliance with the terms of this Agreement. FDA meetings initiated by an MCM Partner to which Recipient's representatives may be invited, or correspondence exchanged between such MCM Partners and FDA which may be provided to Recipient, are outside the scope of this provision.

13.3 Regulatory Filings. The Recipient shall file, maintain, and update one or more confidential Type III drug master files with the FDA necessary to the performance of this Agreement (collectively, "DMF"). Each DMF shall include the information necessary to support MCM Partner regulatory submissions. At the MCM Partner's request, Recipient shall provide relevant MCM Partners with a Letter of Authorization to use in referencing Recipient's DMF(s) as part of the MCM Partners' regulatory submissions to FDA. Notwithstanding the foregoing, the Government acknowledges that a DMF is not applicable to Recipient's performance under this Agreement and will not be filed with FDA.

14. Termination

Termination and Enforcement procedures are in accordance with 32 CFR §34.51 through §34.52.

15. Disputes

15.1 ADR. 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 Agreements Officer. Alternately, the Parties may agree to explore and establish an Alternate Disputes Resolution procedure to resolve this dispute.

15.2 Claims.

a. Recipient Claims. The Recipient shall submit claims arising out of this Agreement to the Agreements Officer. Claims shall specify the nature and basis for the relief requested and shall include all data and relevant facts in support of the claim.

b. DoD Component Claims. Claims by a DoD Component shall be the subject of a written decision by the Agreements Officer.

15.3 Agreements Officer Decisions. Within 60 calendar days after receipt of a written claim, the Agreements Officer shall:

a. Prepare a written decision, which shall include the basis for the decision, the relevant facts on which the decision is based, and the identity and address of the cognizant Appeal Authority; or

b. Notify the Recipient of a date when the decision will be rendered. The notice shall address why additional time is needed and what, if any, additional information is required from the Recipient to adjudicate the claim.

The Agreements Officer's decision is final, unless appealed. In the event of an appeal, the Parties shall endeavor to use ADR procedures to the maximum extent practicable.

15.4 Formal Administrative Appeals

15.4.1 Appeal Authority. The Agreements Officer of the ACC-APG-RTP is the Appeal Authority to decide formal, administrative appeals under this Agreement. If the Agreements Officer of the ACC-APG-RTP is unable to serve in this capacity, the Division Chief of ACC-APG-RTP Division shall so serve.

15.4.2 The Recipient may appeal an Agreements Officer's decision within 90 calendar days of receiving the decision by filing a written notice of appeal with the Appeal Authority and the Agreements Officer.

15.4.3 If the Parties elect to use ADR following the Agreement Officer's decision, the remaining portion of the 90- day period for filing notice of appeal shall be tolled during the period running from the date the Parties agree in writing to utilize ADR to the date either (1) an ADR decision is issued or (2) one Party notifies the other in writing that it is abandoning the ADR process.

15.4.4 Appeal File. Within 30 calendar days after receipt of the notice of appeal, the Agreements Officer shall forward to the Appeal Authority and the Recipient the appeal file, which shall include copies of all documents relevant to the appeal. The Recipient may supplement the file with additional documents it deems relevant. Either Party may supplement the file with a memorandum in support of its position, or the Appeal Authority may request additional information from the Parties.

15.4.5 Decision. The appeal shall be decided solely on the basis of the written record, unless the Appeal Authority decides to conduct fact-finding or an oral hearing on the appeal. Any fact-finding or hearing shall be conducted using procedures that the Appeal Authority deems appropriate. The decision of the Appeal Authority shall be final.

15.5 Non-exclusivity of remedies. 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.

16. Reports & Distribution

(b) (4)

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(b) (4)

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

17. Modification of the Agreement

17.1 Limitation. In no event shall any understanding or agreement, modification, change order, or other matter in deviation from the terms of this Agreement between the Recipient and a person other than the Agreements Officer be effective or binding upon the Government. All such actions must be formalized by a proper contractual document executed by the Agreements Officer. The only method by which this Agreement can be modified is by a formal, written modification signed by the Agreements Officer. No other communications, whether oral or in writing, shall modify this Agreement.

17.2 Recommendation. Modifications to this Agreement may be proposed by either Party. Recipient recommendations for any modifications to this Agreement, including justifications to support any changes to the proposal (inclusive of proposal revisions, proposal appendices, and the collaboration plan), as incorporated by reference, shall be submitted in writing to the Government Program Manager with a copy to the Agreements Officer. The Recipient shall detail the technical, chronological, and financial impact of the proposed modification to the program. Changes are effective only after this Agreement has been modified. The Agreements Officer is responsible for the review and verification of any recommendations.

17.3 Unilateral or Minor. The Agreements Officer may unilaterally issue administrative Agreement modifications (e.g., changes in the paying office or appropriation data, or changes to Government personnel identified in this Agreement, etc.). All other modifications shall be the result of bilateral agreement of the Parties. The Government may make minor or administrative Agreement modifications unilaterally.

18. Miscellaneous

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

18.2 Entire Agreement. This Agreement, inclusive of the collaboration plan(s), constitutes the entire Agreement between the Parties concerning the subject matter hereof and supersedes any prior understandings or written or oral Agreement relative to said matter. In the event of a conflict between the terms of this Agreement, the terms of this Agreement shall govern.

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

(b) (4)

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

(b) (4)

18.5 Non-Assignment. This Agreement may not be assigned by any Party except by operation of law resulting from the merger of a Party into or with another corporate entity, sale of substantially all of the assets of a Party, or other similar change of control transaction.

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

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

18.8 Foreign Access to Technology & Domestic Manufacturing

18.8.1 Activities Abroad. The Recipient shall assure that Project activities carried on outside the United States are coordinated as necessary with appropriate Government authorities and that appropriate licenses, permits, or approvals are obtained prior to undertaking proposed activities. The awarding agency does not assume responsibility for Recipient compliance with the laws and regulations of the country in which the activities are to be conducted.

18.8.2 Export. The Parties understand that information and materials provided pursuant to or resulting from this Agreement may be export controlled, sensitive, for official use only, or otherwise protected by law, executive order, or regulation. The Recipient is responsible for compliance with all applicable laws and regulations. Nothing in this Agreement shall be construed to permit any disclosure in violation of those restrictions.

18.8.3. Exclusive right to use or sell the technology in the United States must, unless the Government grants a waiver, require that products embodying the technology or produced through the use of the technology will be manufactured substantially in the United States (37.875).

18.9 Performance by Affiliates.

The Government acknowledges and agrees that Recipient may perform its obligations under this Agreement through one or more of its affiliates, provided that Recipient will be responsible for the full and timely performance as and when due under, and observance of, all the covenants, terms, conditions and agreements set forth in this Agreement by its affiliates. It is acknowledged that certain costs relating to the project and covered by this Agreement may be incurred by the Recipient's US affiliate Hyclone Laboratories LLC.

18.10 Enforcement

This Agreement may only be enforced by the parties hereto.

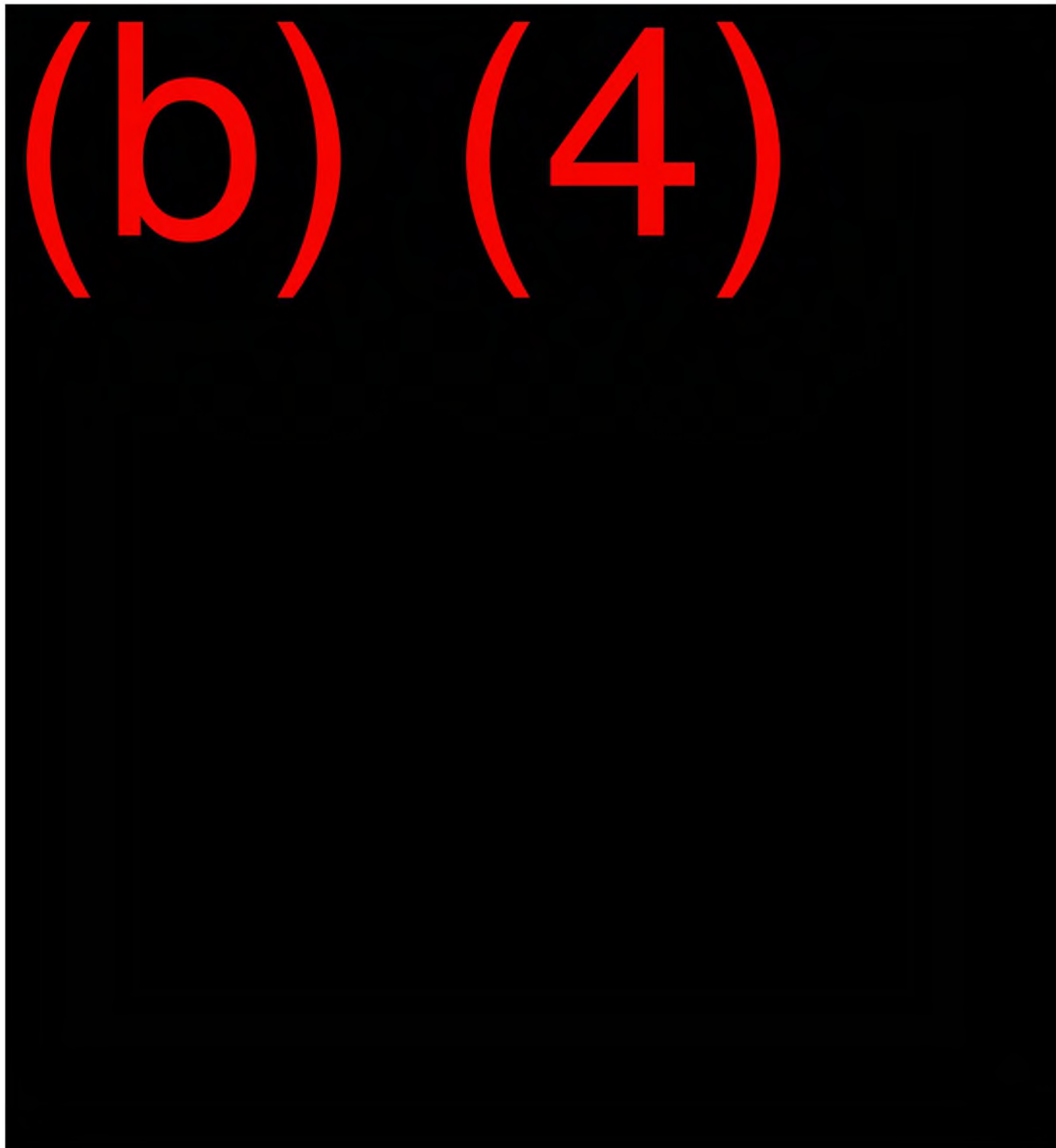
ATTACHMENT 3 - ADDITIONAL REPORTING REQUIREMENTS

1.1	(b) (4)	(b) (4)
1.2	(b) (4)	(b) (4)

		(b) (4) [Redacted]
1.3	(b) (4) [Redacted]	(b) (4) [Redacted]
1.4	(b) (4) [Redacted]	(b) (4) [Redacted]
1.5	(b) (4) [Redacted]	• (b) (4) [Redacted]

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1.6	<p>(b) (4)</p>	<p>(b) (4)</p> <p>[Redacted text]</p>

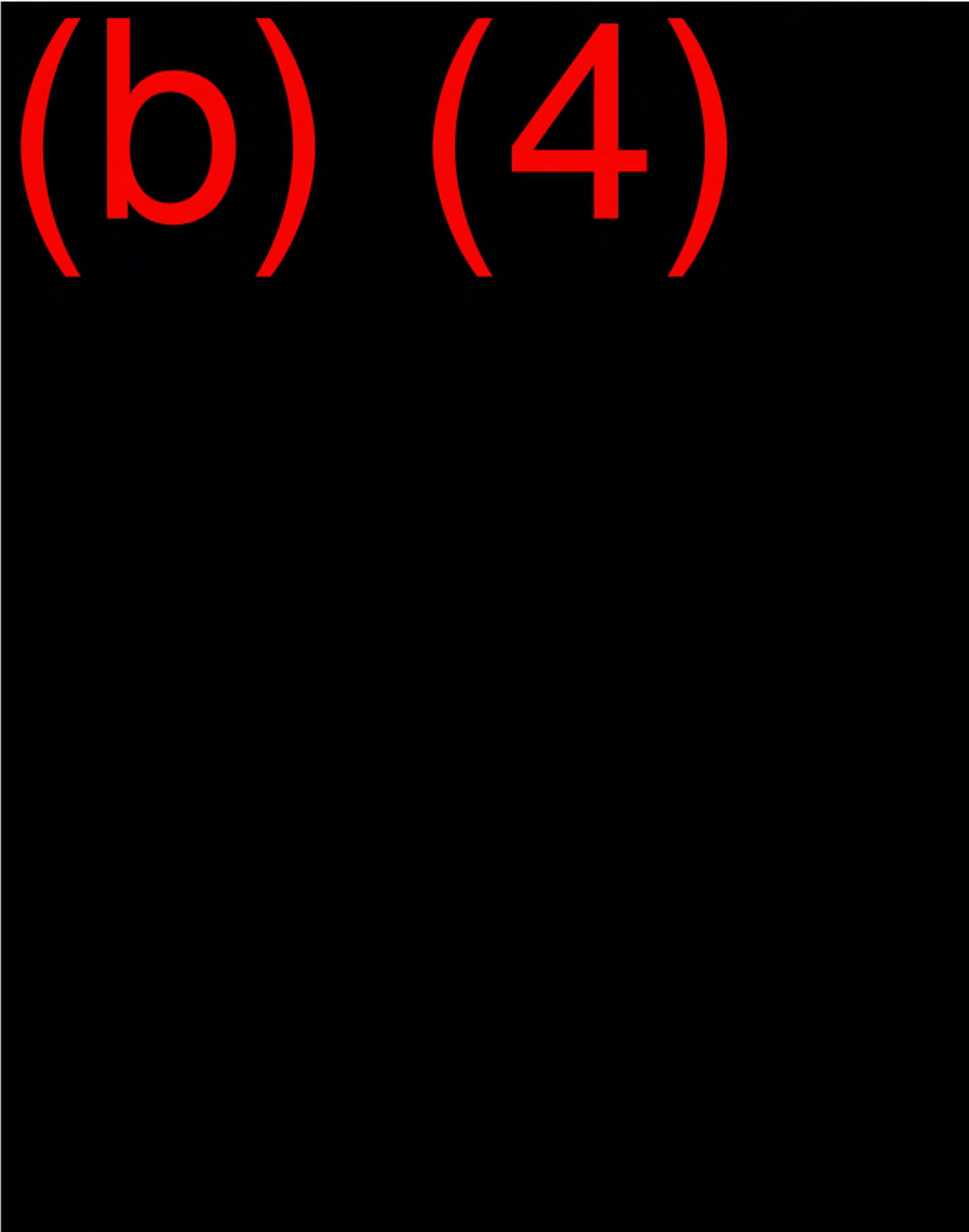
Appendix 4 Clause for all other Other Transaction Authority Agreements



(b) (4)



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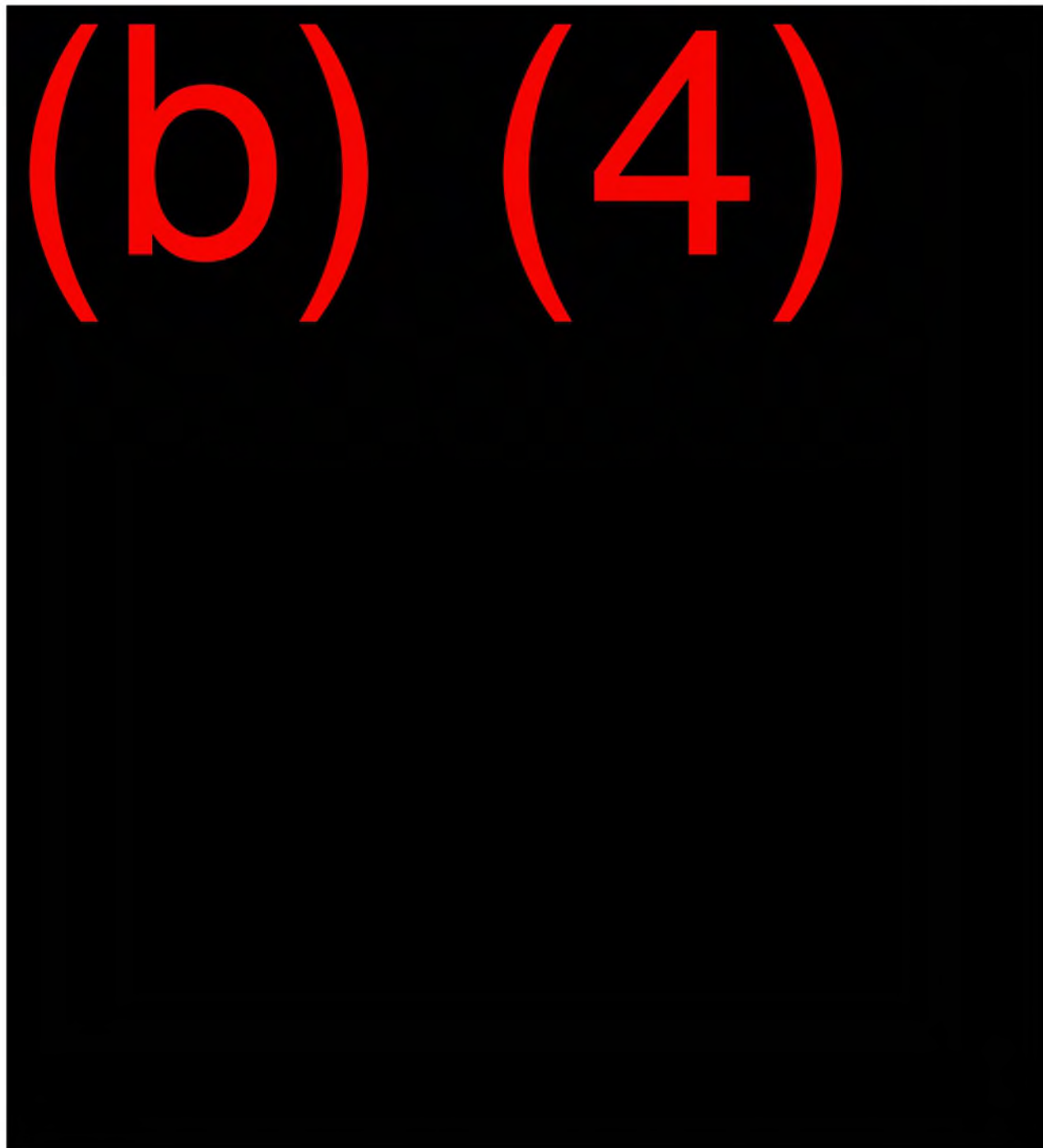


(b) (4)



(b) (4)



**Key Personnel**

Any key personnel specified in this Agreement are considered to be essential to work performance. At least thirty (30) calendar days prior to the Recipient voluntarily diverting any of the specified individuals to other programs or contracts the Recipient shall notify the Agreements Officer and shall submit a justification for the diversion or replacement and a request to replace the individual. The request must identify the proposed replacement and provide an explanation of how the replacement's skills, experience, and credentials meet or exceed the requirements of the contract (including, when applicable, Human Subjects Testing requirements). If the employee of the Recipient is terminated for cause or separates from the Recipient voluntarily with less than thirty (30) calendar-day notice, the

Recipient shall provide the maximum notice practicable under the circumstances. The Recipient shall not divert, replace, or announce any such change to key personnel without the written consent of the Agreement Officer. The agreement will be modified to add or delete key personnel as necessary to reflect the agreement of the parties. The individuals, as shown in the Recipient's proposal, are determined to be key personnel.

Substitution of Key Personnel

The Recipient agrees to assign to the agreement those persons whose resumes/CVs were submitted with the proposal who are necessary to fill the requirements of the agreement. No substitutions shall be made except in accordance with this clause.

All requests for substitution must provide a detailed explanation of the circumstance necessitating the proposed substitution, a complete resume for the proposed substitute and any other information requested by the contracting officer to approve or disapprove the proposed substitution. All proposed substitutes must have qualifications that are equal to or higher than the qualifications of the person to be replaced. The agreement officer or authorized representative will evaluate such requests and promptly notify the recipient of his approval or disapproval thereof. The recipient further agrees to include the substance of this clause in any subaward, which may be awarded under this agreement.

Disclosure of Information

Performance under this agreement may require the Recipient to access non-public data and information proprietary to a Government agency, another Government Contractor/Recipient or of such nature that its dissemination or use other than as specified in the work statement would be adverse to the interests of the Government or others. Neither the Recipient, nor Recipient personnel, shall divulge nor release data nor information developed or obtained under performance of this agreement, except authorized by Government personnel or upon written approval of the AO in accordance with OWS or other Government policies and/or guidance. The Recipient shall not use, disclose, or reproduce proprietary data that bears a restrictive legend, other than as specified in this agreement, or any information at all regarding this agency.

The Recipient shall comply with all Government requirements for protection of non-public information. Unauthorized disclosure of nonpublic information is prohibited by the Government's rules. Unauthorized disclosure may result in termination of the agreement, replacement of a Recipient employee, or other appropriate redress. Neither the Recipient nor the Recipient's employees shall disclose or cause to be disseminated, any information concerning the operations of the activity, which could result in, or increase the likelihood of, the possibility of a breach of the activity's security or interrupt the continuity of its operations.

No information related to data obtained under this agreement shall be released or publicized without the prior written consent of the AOR, whose approval shall not be unreasonably withheld, conditioned, or delayed, provided that no such consent is required to comply with any law, rule, regulation, court ruling or similar order; for submission to any government entity; for submission to any securities exchange on which the Recipient's (or its parent corporation's) securities may be listed for trading; or to third parties relating to securing, seeking, establishing or maintaining regulatory or other legal approvals or compliance, financing and capital raising activities, or mergers, acquisitions, or other business transactions.

Publications and Publicity

The Recipient shall not release any reports, manuscripts, press releases, or abstracts about the work being performed under this agreement without written notice in advance to the Government.

(a) Unless otherwise specified in this agreement, the recipient may publish the results of its work under this agreement. The Recipient shall promptly send a copy of each submission to the AOR for security review prior to submission. The recipient shall also inform the AOR when the abstract article or other publication is published, and furnish a copy of it as finally published.

(b) Unless authorized in writing by the AO, the Recipient shall not display Government logos including Operating Division or Staff Division logos on any publications.

(c) The Recipient shall not reference the products(s) or services(s) awarded under this agreement in commercial advertising, as defined in FAR 31.205-1, in any manner which states or implies Government approval or endorsement of the product(s) or service(s) provided.

(d) The Recipient shall include this clause, including this section (d) in all subawards where the subawardee may propose publishing the results of its work under the subaward. The Recipient shall acknowledge the support of the Government whenever publicizing the work under this agreement in any media by including an acknowledgement substantially as follows:

"This project has been funded in whole or in part by the U.S. Government under Agreement No. W911NF2030007. The US Government is authorized to reproduce and distribute reprints for Governmental purposes notwithstanding any copyright notation thereon."

Confidentiality of Information

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

b. The Agreements Officer and the Recipient may, by mutual consent, identify elsewhere in this agreement specific information and/or categories of information which the Government will furnish to the Recipient or that the Recipient is expected to generate which is confidential. Similarly, the Agreement Officer and the Recipient may, by mutual consent, identify such confidential information from time to time during the performance of the agreement. 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 Recipient 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 Recipient is uncertain with regard to the proper handling of material under the agreement, or if the material in question is subject to the Privacy Act or is confidential information subject to the provisions of this article, the Recipient shall obtain a written determination from the Agreement Officer prior to any release, disclosure, dissemination, or publication.

f. Agreement 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-awardees.

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

Whenever performance of this agreement provides access to another Contractor's proprietary information, the Recipient 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 agreement. An executed copy of all proprietary information agreements by individual personnel or on a corporate basis shall be furnished to the AO within fifteen (15) calendar days of execution.

Institutional Responsibility Regarding Investigator Conflicts of Interest

The Institution (includes any Recipient, 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, through 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 Section K - 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 Agreement Officer of the corrective action taken or to be taken. The Agreement 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 Agreement 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 Agreement 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 Agreement 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 Agreement Officer may be necessary until the matter is resolved.

If the Agreement 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.

Attachment 5 – MCM Partner List



Section B - Supplies or Services and Prices

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0001	COVID-19 Capacity Expansion FOB: Destination PSC CD: K065	1	Job		\$32,190,000.00
				ESTIMATED COST	\$32,190,000.00

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000101	Cytiva COVID-19 Efforts Cytiva COVID-19 Efforts PURCHASE REQUEST NUMBER: 0011546770				\$0.00
	ACRN AA CIN: GFEBS001154677000001			ESTIMATED COST	\$0.00 \$32,190,000.00

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0002 OPTION.	Option (b) (4)		Each		NSP
				ESTIMATED COST	\$0.00

Section F - Deliveries or Performance

DELIVERY INFORMATION

CLIN	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
0001	POF (b) (4) ██████████ ██████████	N/A	JPM MEDICAL MEDICAL COUNTERMEASURE SYSTEMS 1564 FREEDMAN DRIVE FORT DETRICK, MD MD 21702 301-619-7298 FOB: Destination	W56XNH
000101	N/A	N/A	N/A	N/A
0002	POF (b) (4) ██████████ ██████████	N/A	JPM MEDICAL MEDICAL COUNTERMEASURE SYSTEMS 1564 FREEDMAN DRIVE FORT DETRICK, MD MD 21702 301-619-7298 FOB: Destination	W56XNH
0003	POF (b) (4) ██████████ ██████████	N/A	(SAME AS PREVIOUS LOCATION) FOB: Destination	W56XNH
0004	POF (b) (4) ██████████ ██████████	N/A	(SAME AS PREVIOUS LOCATION) FOB: Destination	W56XNH
0005	POF (b) (4) ██████████ ██████████	N/A	(SAME AS PREVIOUS LOCATION) FOB: Destination	W56XNH

Section G - Contract Administration Data

ACCOUNTING AND APPROPRIATION DATA

AA: 0212020202120400000664643255 S.0074658.5.12.3 6100.9000021001
COST CODE: A5XAH
AMOUNT: \$32,190,000.00

ACRN	CLIN/SLIN	CIN	AMOUNT
AA	000101	GFEB001154677000001	\$32,190,000.00