

Subject: ACC-NJ FOIA Office Responses to FOIA Cases # FA-21-0029 and # FA-21-0030

Date: Friday, May 14, 2021 at 10:46:20 AM Eastern Daylight Time

From: USARMY PICA ACC Mailbox ACCNJ FOIA REQUESTS

To: FOIA

CC: Schneider, Nadine K CIV USARMY ACC (USA)

EXTERNAL SENDER

Dear American Oversight,

This responds to your October 15, 2020 request for copies of the agreements between Advanced Technology International, Inc. and Novavax, Pfizer, BioNTech, Sanofi Pasteur, GlaxoSmithKline and Johnson & Johnson/Janssen regarding the development of coronavirus vaccines or therapeutics. The Department of Army FOIA Office referred your request (FA-21-0441) to this office on March 4th, 2021 and was assigned ACC-NJ FOIA case # FA-21-0029.

This email also acknowledges your October 15, 2020 request for all records reflecting the terms and/or conditions of contract(s), amendment(s), memorandum of understanding(s), or other written agreement(s) between ATI and Novavax, Pfizer, BioNTech, Sanofi Pasteur, GlaxoSmithKline and Johnson & Johnson/Janssen regarding the development of coronavirus vaccines or therapeutics. The Department of Army FOIA Office also referred your request (FA-21-0442) to this office on March 4, 2021 and was assigned ACC-NJ FOIA case # FA-21-0030.

Releasable versions of the requested agreements/records are available to the public on the U.S. Department of Health & Human Services' FOIA Reading Room website, located underneath "Operation Warp Speed": <https://www.hhs.gov/foia/electronic-reading-room/index.html>.

Please let me know if you have any questions.

Sincerely,
Nadine

Nadine Schneider
DA Civilian
Procurement Analyst
US Army Contracting Command-New Jersey
Mission Execution Office
Phipps Road, Bldg. 1610
Picatinny Arsenal, NJ 07806-5000
Phone: 973-724-4800
DSN: 880-4800
Email: nadine.k.schneider.civ@mail.mil

AWARD/CONTRACT		1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)		RATING		PAGE OF PAGES 1 21	
2. CONTRACT (Proc. Inst. Ident.) NO. W911SR2030001		3. EFFECTIVE DATE 20200701		4. REQUISITION/PURCHASE REQUEST/PROJECT NO. 0011506628-0002			
5. ISSUED BY USA CONTRACT NG CMD-APG - W911SR EDGEWOOD CONTRACTING DIVISION 8456 BRIGADE STREET BLDG E4215 ABERDEEN PROV NG GROUND MD 21010-5401		CODE W911SR		6. ADMINISTERED BY (If other than Item 5) DCMA SPR NGF ELD - S3101A BLDG 93 PICATINNY NJ 07806-5000		CODE S3101A	
7. NAME AND ADDRESS OF CONTRACTOR (No., street, city, county, state and zip code) BECTON, DICKINSON AND COMPANY 1 BECTON DR FRANKLIN LAKES NJ 07417-1880				8. DELIVERY [] FOB ORIGIN [X] OTHER (See below)			
				9. DISCOUNT FOR PROMPT PAYMENT Net 30 Days			
				10. SUBMIT INVOICES 1 (4 copies unless otherwise specified) TO THE ADDRESS SHOWN IN:		ITEM Section G	
CODE 06531		FACILITY CODE		11. SHIP TO/MARK FOR CODE W56XNH BIOMEDICAL ADVANCED RESEARCH DEVELOPMENT (b) (6) ROOM 23E07 O'NEILL HOUSE OFFICE BUILD NG WASHINGTON DC 20515			
				12. PAYMENT WILL BE MADE BY CODE HQ0337 DFAS-COLUMBUS CENTER NORTH ENTITLEMENT OPERATIONS P.O. BOX 182266 COLUMBUS OH 43218-2266			
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							\$42,303,230.00
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	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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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 copy 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)				20A. NAME OF CONTRACTING OFFICER (b) (6) TEL: (b) (6) EMAIL: (b) (6)			
19B. NAME OF CONTRACTOR Becton, Dickinson, and Company BY (b) (6) (Signature of person authorized to sign)		19C. DATE SIGNED 7/1/2020		20B. UNITED STATES OF AMERICA (b) (6) (b) (6) BY (b) (6) (Signature of Contracting Officer)		20C. DATE SIGNED 20200701	

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Section B - Supplies or Services and Prices

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0001	TECHNOLOGY INVESTMENT AGREEMENT COST Technology Investment Agreement (TIA) for Expanding Domestic Production of Needles and Syringes in accordance with (IAW) Recipient Proposal dated 25 June 2020. FOB: Destination PSC CD: 6515		Job		\$42,303,230.00 NTE
				ESTIMATED COST	\$42,303,230.00
ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000101	Funding for CLIN 0001 COST This line item is created for funding purposes only. PURCHASE REQUEST NUMBER: 0011506628-0002				\$0.00
				ESTIMATED COST	\$0.00
	ACRN AA CIN: GFEBS001150662800001				\$42,303,230.00

Section E - Inspection and Acceptance

INSPECTION AND ACCEPTANCE TERMS

Supplies/services will be inspected/accepted at:

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

Section F - Deliveries or Performance

DELIVERY INFORMATION

CLIN	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
0001	POP 01-JUL-2020 TO 30-JUN-2030	N/A	BIOMEDICAL ADVANCED RESEARCH DEVELOPMENT JOSEPH FIGLIO ROOM 23E07 O'NEILL HOUSE OFFICE BUILDING WASHINGTON DC 20515 FOB: Destination	W56XNH
000101	N/A	N/A	N/A	N/A

Section G - Contract Administration Data

ACCOUNTING AND APPROPRIATION DATA

AA: 0212020202120400000664643255 S.0074658.5.1 6100.9000021001
COST CODE: A5XAH
AMOUNT: \$42,303,230.00

ACRN	CLIN/SLIN	CIN	AMOUNT
AA	000101	GFEB001150662800001	\$42,303,230.00

Section H - Special Contract Requirements

SECTION H

H.1 Key Personnel

H.1.1 Pursuant to HHSAR 352.237-75 (Dec 2015), 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 Contractor voluntarily diverting any of the specified individuals to other programs or agreements the Contractor 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 agreement (including, when applicable, Human Subjects Testing requirements). If the employee of the Contractor is terminated for cause or separates from the Contractor voluntarily with less than thirty (30) calendar-day notice, the Contractor shall provide the maximum notice practicable under the circumstances. The Contractor shall not divert, replace, or announce any such change to key personnel without the written consent of the Agreements Officer. The agreement will be modified to add or delete key personnel as necessary to reflect the agreement of the parties. The following individuals are determined to be key personnel:

H.1.2 Substitution of Key Personnel

H.1.2.1 The Contractor 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.

H.1.2.2 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 Agreements 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 Agreements Officer or authorized representative will evaluate such requests and promptly notify the contractor of his approval or disapproval thereof.

H.1.2.3 The contractor further agrees to include the substance of this clause in any subcontract, which may be awarded under this agreement.

H.2 Disclosure of Information:

H.2.1 Performance under this agreement may require the Contractor to access non-public data and information proprietary to a Government agency, another Government Contractor 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 Contractor, nor Contractor 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 CO. The Contractor 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.

H.2.2 Consistent with HHS Directive 1139, the Contractor shall comply with HHS requirements for protection of non-public information. Unauthorized disclosure of nonpublic information is prohibited by the HHS's rules. Unauthorized disclosure may result in termination of the agreement, replacement of a Contractor employee, or other appropriate redress. Neither the Contractor nor the Contractor'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.

H.2.3 No information related to data obtained under this agreement shall be released or publicized without the prior written consent of the COR, 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 Contractor'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.

H.2.4 Publication and Publicity

H.2.4.1 The contractor 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, for additional information see HHSAR 352.227-70. Publications and Publicity (Dec 2015).

- (a) Unless otherwise specified in this agreement, the contractor may publish the results of its work under this agreement. The contractor shall promptly send a copy of each submission to the COR for security review prior to submission. The contractor shall also inform the COR 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 contractor shall not display the HHS logo including Operating Division or Staff Division logos on any publications.
- (c) The contractor 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 HHS approval or endorsement of the product(s) or service(s) provided.
- (d) The contractor shall include this clause, including this section (d) in all subcontracts where the subcontractor may propose publishing the results of its work under the subcontract. The contractor shall acknowledge the support of the Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority 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 with Federal funds from the Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, under Agreement No. W911SR2030004."

H.3 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 Contractor may, by mutual consent, identify elsewhere in this agreement 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 Agreements Officer and the Contractor 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 agreement that information to be utilized under this agreement, 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 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 Contractor shall obtain a written determination from the Agreements Officer prior to any release, disclosure, dissemination, or publication.
- f. Agreements 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.

H.4 Organizational Conflicts of Interest:

H.4.1 Performance under this agreement 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 agreement, 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 agreement, upon determination that an OCI has occurred.

H.4.2 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 Contractor's performance of this agreement, 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.

H.4.3 The Contractor shall notify the Agreements 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 Agreements Officer to either avoid or mitigate any such OCI. The Agreements Officer will have sole discretion in accepting the Contractor's mitigation plan. In the event the Agreements 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 agreement requirements related to OCI.

H.4.4 Whenever performance of this agreement provides access to another Contractor's proprietary information, the Contractor shall:

(1) 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 CO within fifteen (15) calendar days of execution.

H.5 Operations Security (OPSEC)

H.5.1 The contractor shall develop and submit an OPSEC Standing Operating Procedure (SOP)/Plan within 30 calendar days of agreement award, to be reviewed and approved by the Government OPSEC lead for this effort. The final OPSEC plan, must address the Government's identified Critical Information List (CIL)

- a) All contractors supporting this effort must complete OPSEC Computer Based Training (CBT) that can be accessed via the (Insert applicable website here).

H.6 Security

H.6.1 The contractor shall develop a comprehensive security plan that complies with the attached BARDA Security Requirements (Attachment C). The Recipient's plan shall be delivered to the Government within 30 days of award. The contractor shall also ensure all subcontractors, consultants, researchers, etc. performing work on behalf of this effort, comply with all BARDA security requirements and prime contractor security plans.

- a) ASPR will review in detail and submit comments within ten (10) business days to the Agreements Officer (AO) to be forwarded to the Contractor. The Contractor shall review the Draft Security Plan comments,

and, submit a Final Security Plan to the U.S. Government within thirty (10) calendar days after receipt of the comments.

- b) The Security Plan shall include a timeline for compliance of all the required security measures outlined by BARDA.
- c) Upon completion of initiating all security measures, the Contractor shall supply to the Agreements Officer a letter certifying compliance to the elements outlined in the Final Security Plan.

Section I - Contract Clauses

TERMS AND CONDITIONS

TECHNOLOGY INVESTMENT AGREEMENT

between

Becton, Dickinson and Company

and

**Department of Defense,
U.S. Army Contracting Command –Aberdeen Proving Ground,
Natick Contracting Division & Edgewood Contracting Division
(ACC-APG, NCD & ECD)**

on behalf of

Biomedical Advanced Research and Development Authority (BARDA)

for

Expanding Domestic Production of Needles & Syringes

Agreement No: W911SR2030001

Total Amount of Government Funding for the Agreement: \$42,303,230.00

Total Cost Share for the Agreement: USG 60% --- BD 40%

Total Estimated Value of the Agreement: \$70,505,383.00

Effective Date: 1 July 2020

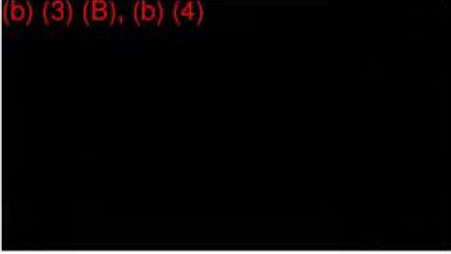
Term of Agreement: Ten (10) Years after Date of Award

TECHNOLOGY INVESTMENT AGREEMENT TERMS AND CONDITIONS

ARTICLES

1. Scope of Agreement
2. Term of Agreement
3. Order of Precedence
4. Program/Administrative Management
5. Financial Management & Payment
6. Accounting & Audit
7. Purchasing & Title
8. Cost Sharing
9. Government Preference
10. Records Retention & Government Access
11. Intellectual Property & Patent Rights
12. Data Rights
13. FDA Regulatory Requirements
14. Termination
15. Disputes
16. Reports & Distribution
17. Modification
18. Miscellaneous

(b) (3) (B), (b) (4)



RECITALS

This Agreement is entered into between the United States of America, Department of Defense, represented by ACC-APG, NCD & ECD ("Government") and Becton, Dickinson and Company, ("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 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 MCS BAA Area of Interest is Mission Area 1, Medical Biological Prophylaxis.

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 research and other 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: Definitions at Subpart J of 32 CFR Part 37; National Policies at Appendix B, 32 CFR Part 22; Audits at Appendix C of 32 CFR Part 37. This TIA is subject good manufacturing practices (cGMPS) 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 as specifically referenced herein. If this instrument is awarded under the authority at 10 USC §2358, the Bayh-Dole Act, 35 U.S.C. §§ 200-212 applies, as applicable.

1.2 Principal Purpose. The Government and the Recipient agree that the principal purpose of this Agreement is for Government investment into the development/expansion of Recipient's manufacturing capacity for hypodermic safety needles and corresponding syringes in response to the worldwide Coronavirus (COVID-19) global pandemic as described in the Recipient's Final Proposal, hereinafter, the "Plan" or "Project". This effort shall be carried out as set forth in the Recipient's Plan and subsequent revisions, which are hereby incorporated in their entirety. 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, for a period of 10 years, the "term" of the Agreement or "Period of Performance." *Period of performance* means the time during which a recipient or sub-recipient may incur new obligations to carry out the work authorized under an award or sub-award, respectively.

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, or any other Federal statutes directly affecting performance of this Agreement, including attachments where applicable; (b) Federal regulations specifically references; (c) the terms and conditions contained within the Agreement, including any documents incorporated; (d) programmatic requirements.

4. Program/Administrative Management

4.1 Program Management. The Recipient has full responsibility for the project/activity 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 as incorporated. The Recipient must consult the Program Office/Technical Representative through the Agreements Officer before deviating from the objectives or overall program of the research originally proposed. Non-compliance with any award provision of this clause may result in the withholding of funds and or the termination of the award.

4.2 Government Representatives:

(b) (6)

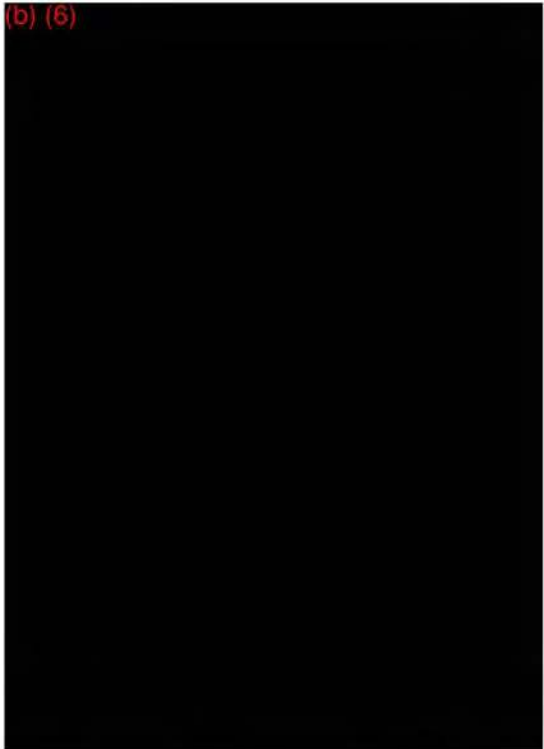
A large section of the document is redacted with black boxes. The redaction covers the entire content of section 4.2 and the beginning of section 4.3. The redaction is composed of several horizontal black bars of varying lengths, some of which are nested, creating a stepped appearance. The text "(b) (6)" is written in red at the top left of the first redacted block.

4.3 Recipients Representatives

(b) (6)

A single large black rectangular box redacts the entire content of section 4.3. The text "(b) (6)" is written in red at the top left of this redacted block.

(b) (6)



5. Financial Management & Payment

5.1 Expenditure-Based. This Agreement is an expenditure type 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."

Payments shall be made on a monthly basis for expenditures incurred up to the agreed upon project ceiling & Government investment funding amount, for the duration of the Period of Performance.

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 AGO 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:

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 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 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: Invoice and Receiving Report (Combo)

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

(3) 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*

<i>Field Name in WAWF</i>	<i>Data to be entered in WA</i>
Pay Official DoDAAC	HQ0337
Issue By DoDAAC	W911SR
Admin DoDAAC	S3101A
Inspect By DoDAAC	W56XNH
Ship To Code	W56XNH

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

- Becton, Dickinson and Company

- Cage Code: 06531
- DUNS: 001292192

(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.

(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.

Administrative Grants Officer (AGO)

(b) (6)



(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 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](#)).

6.2 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.

6.3 Program Income. 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). 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. With the exception of the reimbursements contemplated in Paragraph 9.1, Paragraph 6.3 shall not require the Recipient to provide to the Government any income received from sales of Qualifying Product (as defined below), nor shall it alter the overall cost sharing arrangement in Section [6].

7. Purchasing & Title

7.1 Title to Property Acquired under Agreement. Title to real property, equipment, and supplies or intangible property that are acquired by the Recipient (whether by purchase, construction or fabrication, development, or otherwise) with Government funding vests in the Recipient conditionally as described at 32 CFR 37.685.

7.1.1 Equipment Costs. Pursuant to 32 CFR 37.685 (b)(2), the Recipient is authorized to include the full acquisition cost of equipment as part of the cost of the project.

7.1.2 Property Management. Real property and equipment acquired by the Recipient during the Agreement is subject to the property management standards in 32 CFR 34.21(b) through (d).

7.2 Disposition. Any Federal interest in the real property or equipment remaining after the term will be addressed at the time of property disposition. Disposition will be in accordance with 32 CFR 34.21.

7.3 Purchasing System. If the Recipient currently performs under DoD assistance instruments subject to the purchasing standards in [32 CFR 34.31](#), then that Part applies. Otherwise, the Recipient may use the existing purchasing systems, as long as applicable requirements are flowed down (37.705).

8. Cost Sharing

8.1 To the maximum extent practicable, the recipient must provide at least half of the costs of the project, in accordance with [§ 37.215](#). *Total value* of the TIA means the total amount of costs that are currently expected to be charged to the award over its life, which includes amounts for the Federal share and any non-Federal cost sharing or matching required under the award; and any options, even if not yet exercised, for which the costs have been established in the award.

8.2 Notwithstanding 8.1 to the contrary, the Government funding is estimated to represent approximately 60% of the overall amount necessary to accomplish the scope of work cited in the proposal (inclusive of all proposal revisions and appendices). The Recipient agrees to provide the resources in the manner shown in their proposal.

8.3 Failure of either Party to provide its respective total contribution may result in a unilateral modification to this Agreement by the AO to reflect proportional reduction in funding for the other Party.

9. Government Preference

9.1 Pricing. During the term of the Agreement, the Recipient agrees that, in the event that it enters into a Group Purchasing Organization (GPO) contract with a Qualifying Third Party (as defined below) with respect to a Qualifying Product (as defined below) with a per unit GPO price lower than that offered for the same Qualifying Product to the Government, the Recipient shall (i) promptly notify the Agreements Officer in writing of the lower price and (ii) extend the lower price to all future sales of the Qualifying Product to the Government. For any purchases that were made after the lower price was first extended to the Qualifying Third Party, the Recipient shall reimburse the Government, the difference between the lower price provided to the Qualifying Third Party and the price provided to the Government, multiplied by the volume/quantity provided after the lower price was first extended. Such reimbursement shall occur within thirty days (30) of the Recipient discovering that the lower price was given to the Qualifying Third Party. Notwithstanding the foregoing, the Parties may agree to apply the reimbursement toward additional quantities/volume of Qualifying Product required by the Government. For the purposes of this Article, (a) "Group Purchasing Organization (GPO)" means an entity that aggregates purchasing volume of healthcare item(s) to realize savings and efficiencies (b) "Qualifying Third Party" means the national GPO in the United States that represents the largest volume of total dollar sales of Qualifying Products in the aggregate with Recipient, as determined on an annual basis by Recipient, and communicated to the Agreements Officer and (c) a "Qualifying Product" is a syringe or needle manufactured, in whole or in part, utilizing equipment funded under this Agreement.

9.2 Precedence. During the period of performance and upon a Presidential Declaration of a Public Health Emergency (a "PHE"), Recipient shall grant the Government the right to place Priority Orders for Qualifying Product so long as the Qualifying Product is intended for use to address the PHE. For purposes of this Section, (a) "Priority Orders" shall mean purchase orders for Qualifying Product that will be prioritized by Recipient as if they were "rated orders" subject to 15 CFR § 700.14.

9.3 Maintenance of equipment and availability of capacity. Recipient agrees that, for the term of this Agreement, it shall maintain all equipment funded by the Agreement in such a way as to ensure that, should the rights established

under 9.2 be in effect, there is capacity equal to that which was available at time of commissioning. Further, the Recipient agrees that should the equipment funded by this agreement be unavailable during a period in which the rights under 9.2 are in effect, the Recipient will make available to the Government equivalent capacity from any existing US-based equipment not funded under this agreement capable of producing Qualifying Product.

9.4. Inspection of equipment. The Recipient grants the Government the right to inspect at any time, upon provision of reasonable advance notice, the equipment funded by this agreement.

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. 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.

11. Intellectual Property & Patent Rights. Reserved; the Government does not anticipate any intellectual property being generated under this Agreement.

12. Data Rights. The Government may only request technical data that is customarily provided to the public with a commercial item or process related to for Qualifying Products, equipment purchased under this Agreement, and repairs or maintenance to said equipment.

13. U.S Food and Drug Administration (FDA) Regulatory Compliance

13.1 Good Manufacturing Practices (GMP) Compliance. To the extent required under the Federal Food, Drug, and Cosmetic Act, 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 FDA pertinent to the manufacturing capability established under this Agreement.

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.

14. Termination

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

15. 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 AO. The AO will review the matter and render a decision in writing. Any such decision is final and binding. In the event of a decision, within 60-calendar days of the referral for review (or such other period as agreed upon by the parties), either party may pursue any right or remedy provided by law in a court of competent jurisdiction as authorized by 28 U.S.C. 1491. Alternately, the parties may agree to explore and establish and Alternate Disputes Resolution procedure to resolve this dispute.

16. Reports & Distribution

16.1 Monthly Progress Reports. Submitted monthly no later than the 10th of the month. Recipient format acceptable. Electronic submission acceptable in MS Office or PDF format. Financial information shall be MS Excel format. Monthly reports shall have Distribution Statement C (U.S. Government and their contractors). Each monthly report shall, at a minimum, contain the following:

- a. Summary of monthly progress for the Recipient's facilities/capabilities associated with this effort
- b. Summary of progress towards established milestones for each facility/capability
- c. Identification of any milestone that is slipping or missed, and discussion of path forward to bring milestone back to schedule, and impact on other milestones
- d. Summary of risks, discussion of potential impacts and efforts to mitigate
- e. Summary of overall schedule and changes from previous month
- f. Financial summary of Recipient costs incurred by month to date, vouchers submitted, and Government payments made

16.2 Quarterly-In-Process Reviews. Scheduled as needed, generally not more frequently than quarterly, at the Recipient's facilities. Duration: eight (8) hours max. Face-to-face or virtual review of previous quarter's activities. Informative in nature to keep BARDA apprised of project progress and to discuss issues that may require joint resolution, such as milestone changes, political impacts on objectives, schedule, funding.

16.3 Annual Financial Status Report. (37.880)

16.4 Final Report. Final Report shall have Distribution Statement C. Final report summarizing stated objectives and the progress that was achieved in meeting those objectives; summary of risks incurred, impacts and mitigation; quantitative discussion of needle & syringe production throughput improvements achieved; financial summary of project; schedule summary for project, comparing original schedule to final schedule; recommendations for path forward as applicable.

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 AO be effective or binding upon the Government. All such actions must be formalized by a proper contractual document executed by the AO. The only method by which this Agreement can be modified is by a formal, written modification signed by the AO. 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 PM with a copy to the AO. 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 AO is responsible for the review and verification of any recommendations.

17.3 Unilateral or Minor. The AO 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 proposal, proposal revision, proposal appendices, and collaboration plan(s), constitutes the entire Agreement between the Parties concerning the subject matter hereof and

supersedes any prior understandings or written or oral Agreement relative to said matter. 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.

18.4 Liability. No Party to this Agreement shall be liable to the other Party for any property consumed, damaged, or destroyed in the performance of this Agreement, unless it is due to the negligence or willful misconduct of the Party or an employee or agent of the Party. In no event shall either Party be liable for special, incidental, or consequential damages arising from or connected with this Agreement.

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.

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 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).

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

SIGNATURES:

Recipient **(b) (6)**

Signature
(b) (6)

(b) (6)

Title
7/1/2020

Date

Government

(b) (6)**(b) (2)**

Signature
(b) (6)

Printed Name
Agreements Officer

Title

Date

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT				1. CONTRACT ID CODE		PAGE OF PAGES 1 89	
2. AMENDMENT/MODIFICATION NO. P00081		3. EFFECTIVE DATE 05-Aug-2020		4. REQUISITION/PURCHASE REQ. NO. SEE SCHEDULE		5. PROJECT NO. (If applicable)	
6. ISSUED BY US ARMY CONTRACTING COMMAND PHIPPS ROAD PICATINNY NJ 07806-5000		CODE W15QKN		7. ADMINISTERED BY (If other than item 6) DCMA ATLANTA 2300 LAKE PARK DRIVE SUITE 300 SMYRNA GA 30080-4091		CODE S1103A	
8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code) ADVANCED TECHNOLOGY INTERNATIONAL ON BEHALF OF THE NCBCDC 315 SIGMA DR SUMMERVILLE SC 29486-7790				9A. AMENDMENT OF SOLICITATION NO.			
				9B. DATED (SEE ITEM 11)			
				X 10A. MOD. OF CONTRACT/ORDER NO. W15QKN-16-9-1002			
				X 10B. DATED (SEE ITEM 13) 08-Apr-2016			
CODE 1G3V8		FACILITY CODE					
11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS							
☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer ☐ is extended, ☐ is not extended.							
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: (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.							
12. ACCOUNTING AND APPROPRIATION DATA (If required) See Schedule							
13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/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) IAW the terms and conditions of the OTA.							
E. IMPORTANT: Contractor ☐ is not, ☒ is required to sign this document and return <u>1</u> 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: martins201688 See "SUMMARY OF CHANGES" for Modification Description.							
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)			
				TEL: (b) (6) / CONTRACTING OFFICER			
				EMAIL: (b) (6)			
15B. CONTRACTOR/OFFEROR (b) (6) Dolan, Mica Sr. Vice President, Contracts and Procurement Aug 4 2020 (Signature of person authorized to sign)		15C. DATE SIGNED		16B. UNITED STATES OF AMERICA (b) (6) BY (Signature of Contracting Officer)		16C. DATE SIGNED 05-Aug-2020	

EXCEPTION TO SF 30
APPROVED BY OIRM 11-84

30-105-04

MULTI-DOD-ARMY-20-2554, 20-2562-A-000022
FAR (48 CFR) 53.243

STANDARD FORM 30 (Rev. 10-83)

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION A - SOLICITATION/CONTRACT FORM

The following have been added by full text:

MOD DESCRIPTION - P00081

The purpose of this modification is to:

- 1) Award RPP 20-11, MCDC2011-004 (Janssen Pharmaceuticals, Inc.) via incorporation of the Terms and Conditions below:
- 2) Add incremental funding to the following project:

RPP 20-11, PRE-20-11 (Janssen): \$1,001,650,000.00 via CLIN 0058.
- 3) Incorporate an updated MCDC Award Tracker, listing the cost/fee and ceiling breakouts for each awarded project via MCDC Award Tracker P00081.

The information, redlines, exchanges, comments provided herein are part of ongoing negotiations that the Parties consider to be Government deliberative process and Janssen trade secrets, commercial or financial information. The Parties are sharing this information, redlines, exchanges, comments under the assurance that each Party shall maintain the confidentiality of the information under the Trade Secrets Act, Procurement Integrity Act, other applicable statutes, regulations, rules, case law, contractual provisions, protective orders or otherwise, and as such, the information, redlines, exchanges, comments provided herein are exempt from disclosure under Exemptions 4 and 5 of the Freedom of Information Act ("FOIA").

P00081 Modification to MCDC OTA No. W15QKN-16-9-1002

BETWEEN

JANSSEN PHARMACEUTICALS, INC.
1125 TRENTON-HARBOURTON ROAD
TITUSVILLE, NJ 08560, USA

AND

THE U.S. ARMY CONTRACTING COMMAND – NEW JERSEY
PHIPPS ROAD, BUILDING 9
PICATINNY ARSENAL, NJ 07806-5000

AND

**THE MEDICAL DEFENSE CBRN DEFENSE CONSORTIUM
C/O ADVANCED TECHNOLOGY INTERNATIONAL**

315 SIGMA DRIVE
SUMMERVILLE, SC 29486

CONCERNING

**COVID-19 PANDEMIC-VACCINE RAPID ADVANCED RESEARCH &
DEVELOPMENT (“ARD”) TO LARGE-SCALE MANUFACTURING**

Modification to MCDC OTA No. W15QKN-16-9-1002: P00081

Project Identifier: MCDC2011-004

Requiring Activity: Joint Program Executive Office for Chemical, Biological, Radiological, and Nuclear Defense (JPEO-CBRND)

Total Amount of the Agreement: \$1,001,650,000

Funds Obligated: \$1,001,650,000

Effective Date of Agreement:

Period of Performance: Contract Award—January 31, 2022 (estimated)

Authority: 10 U.S.C. 2371b, and 10 U.S.C. 2371b(f)

This Agreement is entered into between the United States of America, represented by the Department of Defense ("DoD"), Army Contracting Command-New Jersey; Advanced Technology International ("ATI") as the Consortium Management Firm ("CMF") of the Medical CBRN Defense Consortium; and Janssen Pharmaceuticals, Inc., pursuant to and under U.S. Federal law.

Janssen Pharmaceuticals, Inc.

U.S. Department of Defense

(b) (6)

BY:

(b) (6)

NAME: Peter W. Gerhard
ITS: Agreements Officer, CCNJ-ET

DATE: 04 August 2020

DATE: 05 August 2020

The Medical Defense CBRN Defense
Consortium c/o
Advanced Technology International

BY:

(b) (6)

NAME: Mica Dolan
ITS: VP Contacts and Procurement
DATE: 04 August 2020

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RECITALS

This Project Agreement is an "Other Transaction for Prototype" pursuant to 10 U.S.C. § 2371b. For the avoidance of doubt, this Project Agreement is not a procurement contract, grant, or cooperative agreement. The Federal Acquisition Regulation ("FAR") and the Defense Federal Acquisition Regulation Supplement ("DFARS") do not apply to this Project Agreement except for any provision expressly referenced herein.

This Project Agreement is being entered between the United States Government, as represented by the U.S. Department of Defense, Joint Program Executive Office for Chemical, Biological, Radiological, and Nuclear Defense ("JPEO-CBRND"), the U.S. Department of Health and Human Services, Biomedical Advanced Research and Development Authority ("BARDA"); and Janssen Pharmaceuticals, Inc. on behalf of itself and the Janssen Consortium Members, as defined in 1.2 herein.

Whereas the Public Readiness and Emergency Preparedness Act ("PREP Act") authorizes the Secretary of Health and Human Services (the "Secretary") to issue a Declaration to provide liability immunity to certain individuals and entities ("Covered Persons") against any claim of loss caused by, arising out of, relating to, or resulting from the manufacture, distribution, administration, or use of medical countermeasures ("Covered Countermeasures").

Whereas the Secretary has issued a PREP Act Declaration on 10 March 2020, as amended, (herein referred to as "Secretary's COVID-19 PREP Act Declaration") and declared that the spread of novel Coronavirus ("SARS-CoV-2") or a virus mutating therefrom and the resulting disease, Coronavirus Disease ("COVID-19"), constitutes a public health emergency.

Now therefore, the Parties agree as follows:

Article I. Scope of the Project Agreement

Article I of the Agreement is hereby superseded by the following terms and conditions of this Project Agreement.

Section I.1 Introduction

The development of a safe and effective SARS-CoV-2 vaccine is considered critical to contain the current COVID-19 pandemic and declared health emergency, and help to prevent future outbreaks. Working with its partners under BARDA OTA No. HHSO100201700018C ("BARDA OTA"), Janssen has generated Ad26.COV2.S, an adenovirus Type 26 ("Ad26") replication-incompetent recombinant vector expressing a stabilized SARS-CoV-2 vaccine, Ad26.COV2.S, recombinant ("Ad26.COV2.S"). Ad26.COV2.S has been shown to induce high levels of neutralizing antibodies against SARS-CoV-2 after immunization with a single dose of the vaccine candidate in different animal species. Furthermore, efficacy against SARS-CoV-2 infection has been shown in

Syrian hamsters. Additional preclinical results will be generated over the coming months, e.g. protection in Non-Human Primates ("NHP"). Clinical studies will start soon with the goal to demonstrate safety, immunogenicity and efficacy. Ad26.COVS.2 will be manufactured on PER.C6® TetR cells and large-scale manufacturing will be needed to address the large demand for vaccination of large parts of the population.

The following efforts, while integral to the overall Ad26.COVS.2 program, are outside the scope of this Project Agreement:

- Chemistry, Manufacturing, and Controls ("CMC") development, including manufacturing of Drug Substance ("DS") and Drug Product ("DP") and nonclinical and clinical development of Ad26.COVS.2, partially funded by BARDA OTA No. HHSO100201700018C;
- Large-scale manufacturing DS capacity established at a Janssen facility in Leiden, Netherlands, as well as with a Contracting Manufacturing Organization ("CMO"), Emergent BioSolutions, which is located in Rockville, MD;
- DP capacity established at Catalent in Bloomington, IN;
- Facility construction and modification, equipment purchase, qualification, and technical transfer activities to manufacture both DS and DP domestically;
- Preparation and submission of applications for an Emergency Use Authorization ("EUA") and Biologics License Application ("BLA"); and
- Monitoring, reporting, and healthcare worker, public education, and communications activities related to EUA distribution, which will be discussed and determined during the pre-EUA discussion period, as defined in applicable guidance documents.

For the avoidance of doubt, Catalent and Emergent, described above, are not considered subcontractors under this Project Agreement.

Article I, Section 2 of the Agreement, hereby adopts the following terms and conditions of the Project Agreement. If there is a conflict between the Agreement and the Project Agreement, the Agreement is hereby superseded by the following terms and conditions of this Project Agreement.

Section I.2 Definitions

Academic Research Institution: This term/condition is not applicable to this Project Agreement, and it is hereby self-deleting from the MCD C Base OTA No. W15QKN-16-9-1002.

Affiliate: Any entity that controls, is controlled by, or is under common control with, a Party to this Project Agreement. In this context, "control" shall mean (1) ownership by one entity, directly or indirectly, of at least fifty percent (50%) of the voting stock of another entity; or (2) power of one entity to direct the management or policies of another entity, by contract or otherwise.

Agreement: Reference back to Article I, Section 2 of the MDCDC Base OTA No. W15QKN-16-9-1002.

Agreements Officer (“AO”): Reference back to Article I, Section 2 of the MDCDC Base OTA No. W15QKN-16-9-1002.

Agreements Officer’s Representative (“AOR”): Reference back to Article I, Section 2 of the MDCDC Base OTA No. W15QKN-16-9-1002.

Background Invention: Background Invention means any Invention, or improvement to any Invention, other than a Subject Invention, that was conceived, designed, developed, produced, and/or reduced to practice prior to performance of the Agreement or this Project Agreement, or outside the scope of work performed under the Agreement or this Project Agreement.

Basket: This term/condition is not applicable to this Project Agreement, and it is hereby self-deleting from the MDCDC Base OTA No. W15QKN-16-9-1002.

Cash Contribution: This term/condition is not applicable to this Project Agreement, and it is hereby self-deleting from the MDCDC Base OTA No. W15QKN-16-9-1002.

Confidential Information: Reference back to Article VIII, Section 1 of the MDCDC Base OTA No. W15QKN-16-9-1002.

Consortium Management Firm (“CMF”): Reference back to Article I, Section 2 of the MDCDC Base OTA No. W15QKN-16-9-1002.

Cost Share: This term/condition is not applicable to this Project Agreement, and it is hereby self-deleting from the MDCDC Base OTA No. W15QKN-16-9-1002.

Contracting Activity: Reference back to Article I, Section 2 of the MDCDC Base OTA No. W15QKN-16-9-1002.

Date of Completion: The date on which the period of performance ends.

Data: Recorded information first created in performance of the Project, regardless of form or method of recording, which includes but is not limited to, technical data and software, but does not include Subject Inventions, production/manufacturing know-how, trade secrets, clinical data, or financial, administrative, cost, pricing or management information.

Deliverable(s): Any documentation (e.g. report, Executive Summary, Letter) given to the Government by Janssen to provide the Government with insight into “Janssen’s Manufacturing Capability” (as defined herein) as described in the second column of Table 1-5 in Article I, Section 5 under the heading “Deliverables.”

Development: This term/condition is not applicable to this Project Agreement, and it is hereby self-deleting from the MCD C Base OTA No. W15QKN-16-9-1002.

Disclosing Party: Reference back to Article VIII, Section 1 of the MCD C Base OTA No. W15QKN-16-9-1002.

Effective Date: The date of execution of this Project Agreement by the Parties. If this Project Agreement is executed in counterparts, the Effective Date shall be the date of the last signature.

Field: Means the development and use of a vaccine to protect against COVID-19 disease caused by SARS-CoV-2 infection.

Government: Reference back to Article I, Section 2 of the MCD C Base OTA No. W15QKN-16-9-1002. Also referred to as "USG."

Government Fiscal Year: Reference back to Article I, Section 2 of the MCD C Base OTA No. W15QKN-16-9-1002.

Government Purpose Rights: The rights to (i) use, modify, reproduce, release, perform, display, or disclose Data within the Government without restriction; and (ii) release or disclose Data outside the Government and authorize persons to whom release or disclosure has been made to use, modify, reproduce, release, perform, display, or disclose that Data for Government purposes. Government purposes include competitive procurement, but do not include the rights to use, modify, reproduce, release, perform, display, or disclose Data for commercial purposes or authorize others to do so.

In Kind Contribution: This term/condition is not applicable to this Project Agreement, and it is hereby self-deleting from the MCD C Base OTA No. W15QKN-16-9-1002.

Invention: Any invention or discovery which is or may be patentable under Title 35 of the United States Code.

Janssen Consortium: That group of Janssen Consortium Members that are: (i) Affiliates of one another; and (ii) have agreed with one another to collaborate to perform the objectives and obligations set forth in this Project Agreement.

Janssen Consortium Member: Janssen Pharmaceuticals, Inc. ("JPI") acting on behalf of itself and as an agent of JOM Pharmaceutical Services, Inc. ("JOM"), Janssen Research & Development, LLC ("JRD"), Janssen Vaccines & Prevention B.V. ("JV&P"), Janssen Products, LP ("JPLP") and its other affiliates involved in the work under this Project Agreement, propose to come together to form a consortium to work together with the Government. For purposes of this Project Agreement, JPI will act as the contract holder and liaise with the Government as the point of contact for the other Janssen entities. The Consortium Members include each of JPI, JOM, JRD, JV&P, JPLP and their

Affiliates involved in the work under this Project Agreement, and are collectively referred to throughout the proposal as “Janssen.”

Janssen Manufacturing Capability: Janssen’s Manufacturing Capability (“JMC”) is the commercial manufacturing capability that Janssen either owns, operates, manages, leases, rents or contracts with another party at various locations and facilities in order to produce commercial products entirely at private expense for performance of this Project Agreement. The Government has no license in any background intellectual property, background technical data, or other information that is generated to either scale-up or to operate the JMC.

Janssen Prototype Product Rights: All patent, copyright, trade secret, FDA regulatory filings and rights in data within Janssen’s possession and control to sublicense without infringement of third-party intellectual property or agreements, necessary to make, use, offer for sale and sell the Prototype Product within the US market.

Know-How: Information, practical knowledge, techniques, and skill development created by Recipient in performance of the Prototype Project necessary for the Practical Application of a Subject Invention within the Field.

Limited Rights: The rights to use, modify, reproduce, perform, display, or disclose Data or other information, in whole or in part, within the Government solely for research purposes for the Field. The Government will ensure that disclosed information is safeguarded in accordance with the restrictions of this Project Agreement. The Government may not, without the prior written permission of Recipient, release or disclose Data or other information outside the Government, use Data or other information for competitive procurement or manufacture, release or disclose Data or other information for commercial purposes, or authorize Data or other information to be used by another party.

Milestone: Each event identified in the second column of Table 1-1.

Medical CBRN Defense Consortium (“MCDC”): Reference back to Article I, Section 2 of the MCDC Base OTA No. W15QKN-16-9-1002.

MCDC Executive Committee: Reference back to Article I, Section 2 of the MCDC Base OTA No. W15QKN-16-9-1002.

MCDC Members: Reference back to Article I, Section 2 of the MCDC Base OTA No. W15QKN-16-9-1002.

Nontraditional Defense Contractor: Reference back to Article I, Section 2 of the MCDC Base OTA No. W15QKN-16-9-1002.

Other Transaction Agreement (“OTA”): Reference back to Article I, Section 2 of the MCDC Base OTA No. W15QKN-16-9-1002.

Other Transactions for Prototype Projects: Reference back to Article I, Section 2 of the MCDC Base OTA No. W15QKN-16-9-1002.

Party: Each of ATI as the CMF, Janssen, and the Government (collectively, "Parties").

Payable Milestone: The obligation of the Government, and ATI as the CMF, acting as an agent on the Government's behalf, to pay Project Agreement Holder/Janssen, in accordance with Article V herein, when Janssen has triggered a payment in accordance with Table 1-1 in Article I, Section 3 of this Project Agreement.

Period of Performance: Contract Award through January 31, 2022.

Practical Application: With respect to a Subject Invention, to manufacture, in the case of a composition of product; to practice, in the case of a process or method, or to operate, in the case of a machine or system; and, in each case, under such conditions so as to establish that the Subject Invention is capable of being utilized.

Program Manager: This term/condition is not applicable to this Project Agreement, and it is hereby self-deleting from the MCDC Base OTA No. W15QKN-16-9-1002.

Project: Defined in Article III, Section 1 of this Project Agreement.

Project Agreement ("PA"): Refers to this P00081 Modification of the MCDC OTA No. W15QKN-16-9-1002 entered into amongst: Janssen Pharmaceuticals, Inc., on behalf of the Janssen Consortium Members, herein defined; the U.S. Army Contracting Command-New Jersey; and ATI as the MCDC CMF, including the Statement of Work as defined in Article I, Sections 3-6, all attachments and modifications thereto, which are expressly incorporated into and made a part of the Project Agreement. Also referred to as Project Agreement/Statement of Work.

Project Agreement Holder ("PAH"): The MCDC member is Janssen which was issued the Project Agreement by the CMF and ACC-NJ.

Project Management Lead (PML): This is the individual at Janssen responsible for management of this Project.

Prototype Product: At least one of the 100 million Regimens of SARS-CoV-2 vaccine, Ad26.COVS recombinant resulting from the Prototype Project ("Ad26COVS").

Prototype Project: Janssen's demonstration of its capacity to perform large scale manufacturing domestically, utilizing the Janssen Manufacturing Capability of up to 100 million Regimens of Ad26.COVS.

Receiving Party: Reference back to Article VIII, Section 1 of the MCDC Base OTA No. W15QKN-16-9-1002.

Recipient: Janssen Pharmaceuticals, Inc. acting on its own behalf and on behalf of the Janssen Consortium and each Janssen Consortium Member.

Regimen: A “vaccine regimen” or “regimen” is either: two separate injections of 5×10^{10} viral injections (single/low doses/.25ml) or one single injection of 1×10^{11} viral particles (double/high dose/.5ml). If clinical trials support a different dosing or administration regimen, the Parties will discuss how to proceed and may agree to modify this Project Agreement in response.

Subject Invention (“SI”): Any Invention (ii) where the conception of such Invention and either (a) the first actual reduction to practice or (b) constructive reduction to practice of such Invention occurs in performance of the Project.

Subject Invention (“SI”) Intellectual Property Rights: Patent rights controlled by Recipient that are necessary to practice the Subject Invention in the Field.

Technical Direction Letter (“TDL”): This term/condition is not applicable to this Project Agreement, and it is hereby self-deleting from the MDCDC Base OTA No. W15QKN-16-9-1002.

Technology: Discoveries, innovations and Know-How, whether patentable or not, including computer software, recognized under U.S. law as intellectual creations to which rights of ownership accrue, including, but not limited to, patents, trade secrets, and copyrights first created in the Project and that have not been disclosed to the public, but does not include any Subject Invention.

Third-Party Licensee: A US-based entity whose primary business is contract manufacturing for third parties, and is not currently or in the future controlled or affiliated with any entity or business that sells vaccines or pharmaceutical products directly to consumers, pharmacies, health care providers or Governmental entities.

United States Army Contracting Command – New Jersey Contracting Activity (“ACC-NJ”): Reference back to Article I, Section 2 of the MDCDC Base OTA No. W15QKN-16-9-1002.

White Paper: Reference back to Article I, Section 2 of the MDCDC Base OTA No. W15QKN-16-9-1002.

Other capitalized terms used in this Project Agreement, but not defined herein, shall have the meaning set forth in the MDCDC Base OTA No. W15QKN-16-9-1002.

Section I.3 Prototype Project, Milestones, and Pricing Assumptions and Conditions

Prototype Project. The scope of this Prototype Project is the demonstration by Janssen of the rapid, large scale supply and logistics capability to manufacture and deliver to the Government, 100M Regimens of the Ad26.COVS.S vaccine. Consistent with the Government's objectives under Operation Warp Speed ("OWS"), Janssen intends to employ its proprietary manufacturing technology and processes, in a manner compliant with applicable laws and regulations, including 21 CFR 210 and 211 and the Drug Supply Chain Security Act ("DSCSA") (to the extent required for COVID-19 medical countermeasures, as defined by relevant U.S. Food and Drug Administration ("FDA") guidance), to manufacture and deliver the Ad26.COVS.S vaccine. The successful provision of these Regimens shall establish the effectiveness of a technology capable of potentially providing immediate and long-term solutions to coronavirus infections. While preclinical and clinical activities are described in the Introduction section of this Statement of Work, the Parties acknowledge and agree that such activities are not related to the large-scale manufacturing demonstration and are out-of-scope for this Prototype Project.

This effort constitutes a prototype project because it will be used to evaluate the technical feasibility of completion of the Prototype Project during the ongoing COVID-19 pandemic and unprecedented threats to several components of the Prototype Project. In addition, this is a prototype project because Janssen will demonstrate and prove-out the at-scale, multi-lot proprietary manufacturing activities in order to assess the feasibility to support the necessary quantity of safe and effective regimens required for vaccination of the U.S. population. Successful completion of the Prototype Project will demonstrate Janssen's capability to rapidly manufacture product, which can be further scaled-up to meet mutually agreed to surge requirements with limited advance notification.

Milestones/Payments. One hundred million Regimens of Ad26.COVS.S vaccine will be provided by Janssen to the Government on a Firm Fixed Price ("FFP") per Regimen basis in accordance with the Milestone Payment Schedule. Due to variances in fill/finish yield, Janssen shall invoice for and the Government, through the CMF, shall pay for actual quantities delivered, at a rate of \$10.00 per Regimen. Janssen shall use its reasonably diligent efforts to provide the Government the full 100M Regimens on or before the final delivery date. The Government will be under no obligation to receive or pay for any Regimens that are not made available for delivery according to the schedule defined in Table 1-1, except that (a) deliveries will be considered to be timely made according to the schedule to the extent that they are made up to 30 calendar days after the applicable delivery date, due to delays related to manufacturing, testing, or release, and (b) the Government will be obligated to accept and pay for Regimens that are not timely delivered by an initially applicable delivery date or within the alternative delivery windows identified in this paragraph, to the extent that any delay in delivery is solely attributable to an Excusable Delay Event as defined in Article IX, Section 4 of this Project Agreement. The Government will, at its discretion, have unilateral authority to extend future delivery dates before they have passed to the extent that any of the 100M Regimens are not expected to be delivered according to the schedule defined in Table 1-1; however, Janssen will be under no obligation to deliver Regimens after December 31, 2021, unless mutually agreed to by both Janssen and the Government. For the avoidance of doubt, to the extent there is a shortfall in the amount of Regimens delivered by any given delivery date, which is not

excused or extended by the terms of this paragraph, then Janssen shall be free to dispose of such shortfall in its sole discretion.

Janssen's current production plan contemplates 100% of release of finished Regimens in 2020 and January and February of 2021 will occur in the US. If Janssen changes this plan in any substantial way, it will discuss with the Government adjustments to this Project Agreement that are consistent with the principles established in this section.

On a month-by-month basis, for any Regimen that Janssen manufactures and releases in the United States in excess of the number of Regimens that Janssen planned to release in the United States for delivery under this Project Agreement from January through June 2021 (irrespective of the source of drug substance), the Government will have an option: (i) for the months of January and February 2021, to purchase 100 percent of such excess; and (ii) for all remaining months, to purchase 20 percent of such excess Regimens at a price of, in each case, \$10/Regimen and agrees that Janssen may allocate or sell the remaining amount of such excess at Janssen's sole discretion. For each delivery month identified in Table 1-1, Janssen will notify the Government about any such excess Regimens on or before the 15th of that month, and the Government will have 5 working days after receiving such notice in which to exercise its option. If the Government exercises its option, Janssen will provide the ordered excess Regimens by the delivery date identified in Table 1-1 for the month in which Janssen provided its notice. Any excess Regimens that are delivered in a particular month will be subtracted from the number of Regimens that Janssen would otherwise be required to deliver in the last month of scheduled deliveries as reflected in Table 1-1. In the event that, as the result of the purchase of excess Regimens as contemplated under this paragraph, no delivery is due in the last month of scheduled deliveries as reflected in Table 1-1, any excess Regimens that are delivered in a particular month will be subtracted from the number of Regimens that Janssen would be required to deliver in what would then be the final month in which deliveries under this Project Agreement will take place. Notwithstanding the foregoing, the Government's option may not be exercised in a way that would require Janssen to deliver more than 100 million Regimens under this Project Agreement.

In the event that Janssen is able to commence delivery of Regimens manufactured and released in the United States prior to January of 2021, the Government shall have a right of first refusal to purchase such Regimens as set forth in this Paragraph. The Government's right shall cover hundred (100) percent of such Regimens. Janssen will notify the Government about the availability of such Regimens within fifteen (15) calendar days after learning of their availability. The Government will then have five (5) working days after receiving such notice in which to exercise its right of first refusal. Janssen may allocate or sell any Regimens that the Government does not elect to purchase in its sole discretion. Any purchased Regimens shall be subtracted from the quantity of Regimens Janssen is required to deliver in the last month of scheduled deliveries as reflected in Table 1-1. In the event that any such subtraction results in Janssen being required to deliver no Regimens in the last month of deliveries as reflected in Table 1-1, any additional or subsequent early deliveries will be subtracted from what would then be the final month in which deliveries under this Project Agreement will take place.

Notwithstanding the foregoing, the Government's rights may not be exercised in such a way that would require Janssen to deliver more than 100 million Regimens under this Project Agreement.

Janssen is currently pursuing external validation of its not-for-profit calculation approach for the pricing of its Regimens to ensure it meets its commitment to make the Regimens available on a not-for-profit basis for use in the emergency pandemic, and Janssen is developing a framework under which any profit would be returned to purchasers of the Regimens. The Parties agree that the Government will benefit from the application of these procedures. This Project Agreement will not be closed out until at least one external validation is complete such that an appropriate credit can be completed if the final not-for-profit price per Regimen is determined to be less than \$10. In no case shall the price per Regimen exceed \$10.

Table 1-1: Milestone Payment Schedule

Milestone Number	Milestone Description	Delivery Date	Value
1	2M Regimens of Ad26.COV2.S	On or before 1/31/2021	\$20,000,000
2	10M Regimens of Ad26.COV2.S	On or before 2/28/2021	\$100,000,000
3	25M Regimens of Ad26.COV2.S	On or before 3/31/2021	\$250,000,000
4	25M Regimens of Ad26.COV2.S	On or before 4/30/2021	\$250,000,000
5	25M Regimens of Ad26.COV2.S	On or before 5/31/2021	\$250,000,000
6	13M Regimens of Ad26.COV2.S	On or before 6/30/2021	\$130,000,000
7	Long-term Storage of Drug Product (Option)	(b) (4), (b) (2)	\$1,650,000
Total (FFP)			\$1,001,650,000
Date of Final Delivery			6/30/2021

Pricing Assumptions and Conditions

- 1) Short-term storage not to exceed 30 days and delivery to no more than 10 sites in the continental United States, are included in the \$10/Regimen pricing.
- 2) At the discretion of the Government, Janssen shall provide the Government with up to twelve (12) months storage of up to 100M Regimens of Ad26.COV2.S (Milestone Number 7), (b) (4), (b) (2).
 The Government shall pay Janssen the full FFP amount, as identified in Table 1-1, distributed evenly across each month ordered for long-term storage capacity, with payment for each month due at the end of the applicable month. As applicable, Janssen will invoice the Government less per month for storage to the extent necessary to reflect Janssen storage vendor charges that are lower than expected for each month.

Section I.4 Scope of P00081 Modification

Subject to Article I, Section 1, the following efforts are included in the scope of this Project Agreement/Statement of Work:

Current Good Manufacturing Practice (“cGMP”) manufacturing, fully compliant with 21 CFR 210 and 211 subject to any guidance from, enforcement discretion exercised by, or formal waiver issued by the FDA in connection with COVID-19, of 100M Regimens of Ad26.COV2.S for distribution by the Government upon EUA under Section 564 of the Food, Drug, and Cosmetics (“FD&C”) Act or a biologics licensure granted under Section 351(a) of the Public Health Service (“PHS”) Act by the FDA, including:

- Final DP vaccine presentation will be subject to evaluation and discussion with the appropriate regulatory authorities under the BARDA OTA No. HHSO001201700018C. As such, the Parties understand and agree that the vaccine presentation may change during performance.
- Labeling of EUA Regimens using the date of manufacture, and not expiry, in order to ensure continuous supply of Ad26.COV2.S, recombinant vaccine is maintained and not disrupted when FDA licensure is received.
- Storage of up to 100 million Regimens of Ad26.COV2.S at Janssen or vendor facility.
- Compliance with the DSCSA Sections 581-585 of PL 113-54 (Nov 27, 2013), including product verification, serialization (serialization requirements need to be further evaluated and may impact timelines for delivery), traceability and detection and response requirements, unless exempted under DSCSA or other applicable legal exception, subject to any guidance from, enforcement discretion exercised by, or formal waiver issued by the FDA in connection with COVID-19.
- Shipping, if required, to up to ten (10) USG directed destinations.
- In coordination with the Government, Janssen will conduct a demonstration of the vaccine shipping process prior to the first delivery of doses at a time mutually agreed to by the Parties. Janssen agrees to share specifications and details associated with the shipping process and containers to enable the Government to adequately plan and prepare for potential distribution of the vaccine.

Section I.5 Prototype Deliverables

Table 1-5: Prototype Deliverables

Deliverable Number	Deliverable Description	Due Date	Format	Data Rights
1	Project Kickoff Materials	Within 30 calendar days after award	Agenda, PPT Slides, etc.	Government Purpose Rights
2	Phase 2/3 Clinical Trial Synopsis	Within 7 calendar days after FDA approval	Janssen-determined format	Government Purpose Rights
3	Provision of PL 115-92 (optional)	10/31/2020	n/a	As Described in Agreed upon Letter
4	Weekly Production Updates / Regimen Tracker	Weekly, upon award	Template to be provided by USG	Government Purpose Rights
5	Monthly Business and High-Level Technical Report	On or before the 15 th of each month	Janssen-determined format	Government Purpose Rights
6	EUA Filing	Within 7 calendar days after submission to FDA	Janssen-determined format	Limited Rights***
7	BLA Filing	Within 7 calendar days after submission to FDA	Janssen-determined format	Limited Rights***
8	Delivery of 100M Regimens	According to Table 1-1	n/a	n/a
9	Release documentation for delivered Regimens	According to Table 1-1	Janssen-determined format	Government Purpose Rights
10	Supply Chain Resiliency Plan or Janssen Equivalent	Within 30 calendar days after award	Janssen-determined format	Government Purpose Rights
11	Manufacturing Data Requirement or Janssen Equivalent	Within 30 calendar days after award	Janssen-determined format	Government Purpose Rights
12	Product Development Source Material	Within 30 calendar days after award	Janssen-determined format	Government Purpose Rights
13	Work Location Report or Janssen Equivalent	Within 30 calendar days after award	Janssen-determined format	Government Purpose Rights
14	Facility Security Plan or Janssen Equivalent	Within 30 calendar days after award	Janssen-determined format	Government Purpose Rights
15	Confirmation of Registration and Listing with FDA	Within 7 calendar days of receipt	Janssen-determined format	Government Purpose Rights
16	Formal Written Responses from the FDA	Within 7 calendar days of receipt	n/a	Government Purpose Rights
17	FDA Inspection and Compliance Notices, Observations and Responses	Within 7 calendar days of receipt	n/a	Government Purpose Rights

18	Manufacturing Development Plan*	Within 7 calendar days of completion	Janssen-determined format	Limited Rights***
19	Quality Management Plan**	Within 7 calendar days of completion	Janssen-determined format	Limited Rights***
20	Shipping Specifications and Details	Within 7 calendar days of completion	Janssen-determined format	Government Purpose Rights

* Manufacturing Development Plan. Janssen will, in the level of detail and format that Janssen solely elects (*provided* such format provides a reasonable and industry-standard level of detail), describe the manufacturing process for the vaccine product to ensure conformity with §501(a)(2)(B) of the Food, Drug, and Cosmetics Act (FD&C Act, Title 21 United States Code ("U.S.C.") §351 (a)(2)(B)), regarding GMP. This plan shall describe as such information becomes available to Janssen, but is not limited to, planned or completed drug substance studies; list of excipients and information to support the safety of excipients that, when appropriate, shall be cross-referenced; drug product and formulation development summary from initial concept through final design; physicochemical and biological properties; manufacturing process development and validation program documents; container closure system documents; microbiological attributes documents and plans; compatibility documents (*e.g.*, precipitation); assay development and validation, stability plan; and any associated risks.

** Quality Management Plan. Janssen will, in the level of detail and format that Janssen solely elects (*provided* such format provides a reasonable and industry-standard level of detail), provide a quality management plan which may include, but is not limited to, the quality policy and objectives, management review, competencies and training, process document control, feedback, evaluation, corrective action and preventive action, process improvement, measurement, and data analysis processes. The framework is normally divided into infrastructure, senior management responsibility, resource management, lifecycle management, and quality management system evaluation.

*** Both parties agree that in addition to USG funding for advanced research and development of Janssen's potentially viable vaccine for COVID-19, Janssen independently invested significantly more over a course of decades to develop the platform technology and capability. Accordingly, in recognition of the disproportionate levels of investment, the government accepts limited rights to use certain data that was predominantly developed at Janssen's expense.

All Deliverables intended for the Agreements Officer's Representative ("AOR") shall be delivered.

At least one copy of all data Deliverables shall be sent to: usarmy.detrick.dod-jpeo-cbrnd.mbx.otadeliverable@mail.mil.

Section I.6 Follow-on Production

This Project Agreement/Statement of Work hereby is eligible for the award of a follow-on production contract for Ad26.COVS subject to the requirements of 10 U.S.C. § 2371b (f)(2)(A) and (B) and (f)(3). In accordance with 10 U.S.C. § 2371b(f), and upon successful demonstration of the Prototype Project or at the accomplishment of particularly favorable or unexpected results that would justify transitioning to production (e.g., EUA or BLA), additional production of up to 200M Regimens, may be awarded to partially or completely meet the USG objective of supplying a safe and effective Ad26.COVS to the entire US population. This Project Agreement includes options that are priced at Janssen's global not-for-profit price of \$10/Regimen as described in Article I, Section 3 above, for follow-on production, not to exceed 200 million Regimens. During the performance of the Project Agreement, the Government and Janssen will finalize the scope of production. If the Prototype Project is successful, as described in this Article I, Section 6, the Government may then enter into follow-on production by executing these options through a separate stand-alone production agreement.

Article II. Term and Termination

Section II.1 Term

The Period of Performance for this Project Agreement/Statement of Work is from the date of contract award through January 31, 2022.

Section II.2 Termination

Termination for Vaccine Discontinuation. In the event that (a) Janssen notifies the Government that, as a result of significant emerging safety or efficacy data, Janssen is ceasing efforts to develop the Ad26.COVS, or (b) such a vaccine receives U.S. regulatory approval or authorization on or prior to expiration of the period of performance of this Project Agreement, but such approval or authorization is subsequently withdrawn and, after a reasonable amount of time, the Government determines that the authorization will not be restored or approval will not be granted, the Government will notify Janssen of its intent to terminate this Agreement. Under (a), if Janssen notifies the Government in good faith of a significant safety or efficacy issue, and the Government does not respond within a reasonable amount of time, then Janssen has the right to terminate the Project Agreement.

Janssen shall have no liability to repay the Government for Regimens delivered prior to the notification of termination. Janssen shall be entitled to full payment for Regimens for which manufacturing has been completed, but which have not yet been delivered to the Government. With respect to Regimens for which manufacturing has been initiated but not completed, Janssen shall be entitled to payment of a proportion of the \$10/Regimen price based on a percentage of the work performed toward release and delivery of such Regimens, plus reasonable charges that Janssen can demonstrate to the satisfaction of the Government using its standard record keeping system to have resulted from the

termination, but not to exceed \$10/Regimen. By way of example, these costs may include, but are not necessarily limited to, costs associated with non-cancellable agreements with vendors to obtain manufacturing capacity or supplies in the performance of this Project Agreement. Janssen shall not be required to comply with the cost accounting standards or contract cost principles for this purpose. This paragraph does not give the Government any right to audit Janssen's records. Janssen shall not be paid for any work performed or costs incurred which reasonably could have been avoided.

From and after the effective date of any such termination, Janssen shall have no further obligation to deliver any vaccine Regimens, and the Government shall have no further obligation to accept any such Regimens for delivery. After termination of this Project Agreement, Janssen may sell or transfer to a third party any Regimens that have not been delivered to the Government.

Stop Work Orders. Except as required by applicable law or regulation, or judicial or administrative order, the Government shall not have the authority to issue a stop work order to halt the work contemplated under this Statement of Work.

Section II.3 Extension of Term

The Parties may extend by mutual written agreement the term of this Project Agreement if funding availability and research opportunities reasonably warrant. Any extension shall be formalized through modification of the Project Agreement by the Agreements Officer ("AO") and the Janssen Project Manager ("PM"). If the Recipient desires an extension to the period of performance of this Project Agreement, the Recipient shall submit a request in writing to the AO. Any request for an extension should include a revised milestone/project schedule (if applicable).

Article III. Project Management, Modifications, and Administration

Section III.1 Management and Modifications

Technical and project management of the manufacture and delivery of up to 100 million Regimens of Ad26.COV2.S ("Project") and the anticipated follow-on activities described in Article I, Section 6 above, established under this Project Agreement, shall be managed as detailed in this Article.

- a. **Project Governance.** Janssen is responsible for the overall management of the Prototype Project and related decisions. The Government and Janssen are bound to each other by a duty of good faith in achieving the Prototype Project objectives as defined in Article I. As such, the Government will have continuous involvement with Janssen. Janssen shall provide project results in accordance with the Deliverables schedule identified in Article I.
- b. **Project Management.** Janssen and the Government will each designate an individual responsible for facilitating the communications, reporting, and

meetings between the Parties. For Janssen the individual will serve as PM, and for the Government the individual will be the AOR.

- c. **Project Reviews.** Janssen and the Government will hold periodic project review meetings as determined by the Janssen Project Manager and AOR, however, these meetings shall not occur more frequently than every fourteen (14) calendar days.
- d. **Reviews Resulting in Modifications.** During the performance of this Project Agreement, as described above, it may be necessary to modify the Statement of Work or delivery timeframes. No communications, whether oral or in writing, that purport to change this Project Agreement are valid unless a modification is issued by the AO. The Parties hereby agree that any mutually agreed upon written request for modification shall be executed in an expedited timeframe.
- e. **Bilateral Modifications.** Janssen or the Government may propose modifications to this Project Agreement. A modification that materially changes the obligations of either the Government or Janssen must be in writing and signed by the AO and Janssen's authorized official. Janssen's requests for modifications shall detail the technical and chronological impact of the proposed change on the Statement of Work or delivery timeframes.
- f. **Unilateral Modifications.** The AO may ONLY issue minor or administrative modifications, which do not change the obligations of Janssen in any adverse manner, such as changes to the paying office or appropriations data, or changes to Government personnel identified in the Project Agreement. Unilateral modifications will only be signed by the AO.

Section III.2 Project Agreement Administration

Government Points of Contact:

AO

NAME: (b) (6)
MAILING ADDRESS: Phipps Rd, Picatinny Arsenal, NJ 07806-5000
EMAIL: (b) (6)
PHONE: (b) (6)
AGENCY NAME/DIVISION/SECTION: CCNJ-ET

AOR

NAME: (b) (6)
EMAIL: (b) (6)
PHONE: (b) (6)
AGENCY NAME/DIVISION/SECTION: HHS/ASPR/BARDA

Janssen Points of Contact:**CLM**

NAME:
MAILING ADDRESS:
EMAIL:
PHONE:

(will be provided within 30 calendar days after award)

PM

NAME:
MAILING ADDRESS:
EMAIL:
PHONE:

(will be provided within 30 calendar days after award)

ATI:

Advanced Technology International
MCDC Contracts
315 Sigma Drive
Summerville, SC 29486

Article IV. "PREP ACT" Coverage

In accordance with the Public Readiness and Emergency Preparedness Act ("PREP Act"), Pub. L. No. 109-148, Division C, Section 2, as amended (codified at 42 U.S.C. § 247d-6d and 42 U.S.C. § 247d-6e), as well as the Secretary of Health and Human Service's ("HHS") Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15198 (Mar. 17, 2020, effective Feb. 4, 2020), and amended on April 15, 2020, 85 Fed. Reg. 21012, and on June 8, 2020, 85 Fed. Reg. 34740 (together, the "Prep Act Declaration"):

- (i) This Project Agreement is being entered into for purposes of facilitating the manufacture, testing, development, distribution, administration, and use of "Covered Countermeasures" for responding to the COVID-19 public health emergency, in accordance with Section VI of the PREP Act Declaration;
- (ii) Janssen's performance of this Project Agreement falls within the scope of the "Recommended Activities" for responding to the COVID-19 public health emergency in accordance with Section III of the PREP Act Declaration; and

- (iii) Janssen is a "Covered Person" per Section V of the PREP Act Declaration.

Therefore, in accordance with Sections IV and VII of the PREP Act Declaration, as well as the PREP Act (42 U.S.C. § 247d-6d), the Department of Defense contracting via assisted acquisition on behalf of the HHS, expressly acknowledges and agrees that the HHS Declaration cited above, specifically its language providing immunity from suit and liability is applicable to this Project Agreement, as long as Janssen's activities fall within the terms and conditions of the PREP Act and the PREP Act Declaration.

The Government may not use, or authorize the use of, any products or materials provided under this Project Agreement, unless such use occurs in the United States (or a U.S. territory where U.S. law applies such as embassies, military installations and NATO installations) and is protected from liability under a declaration issued under the PREP Act, or a successor COVID-19 PREP Act Declaration of equal or greater scope. Any use where the application of the PREP Act is in question will be discussed with Janssen prior to use and, if the parties disagree on such use, the dispute will be resolved according to Article VI, "Disputes."

If the Government agrees to provide any additional clarity about the applicability of PREP Act immunity to any maker of a vaccine or pharmaceutical product to prevent or treat SARS-CoV-2, COVID-19, or mutations therefrom, the Government will provide the same clarity to Janssen under this Project Agreement.

Article V. Obligation and Payment

Section V.1 Limitation of Liability

In no case shall the Parties' financial liability for performance exceed the amount obligated under this Project Agreement/Statement of Work.

Section V.2 Fixed Price Payment Method

Payments shall be made in accordance with the payment schedule of this Project Agreement/Statement of Work, as shown in Article I, Section 3 above, provided the designated AOR has verified compliance with the Statement of Work and accomplishment of the stated effort. An acceptable invoice for FFP payments is one that (on the invoice):

- a. contains the date of invoice and the base Agreement number and Project Agreement number;
- b. identifies any associated technical milestones and the progress toward completion of each milestone; and
- c. lists the price contained in each Project Agreement.

Section V.3 Accounting System Requirements

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

Section V.4 Payments and Payment Instructions

- a. The Parties agree that fixed payments will be made for delivery of product or storage. These payments reflect the value received by the Government toward the accomplishment of the goals of this Project Agreement.
- b. Janssen shall submit an original invoice as described in Article V, Section 2, above, via (b) (4) Payment terms are NET 30 days after CMF's receipt of an invoice that meets the conditions of Article V, Section 2 above.
- c. In accordance with Article XII, herein, the Government shall inspect, accept or reject the work as promptly as practicable after submission or completion, unless otherwise specified in this Project Agreement/Statement of Work. Government failure to inspect, accept or reject the work shall not relieve Janssen 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 contract requirements. The remedy for nonconforming is rework by Janssen within reasonably revised timelines.
- d. The Parties hereby agree that reasonable delays in performance of this Project Agreement/Statement of Work shall not be considered nonconforming work, as defined above. The Parties hereby further agree that Janssen has provided timelines based on its best estimates in accordance with the Government's accelerated timeframes and that the nature of vaccine production/manufacturing is inherently complex and in order to ensure appropriate quality, safety and efficacy standards are met, some delays are unavoidable and these delays will be addressed by the Parties under the Governance structure of Article III of this Project Agreement/Statement of Work, as the circumstances dictate at that time. Each delivery identified in Table 1-1 will be made independent of the other deliveries, and a failure to make one or more deliveries will not impact the Parties' obligations with respect to the other deliveries as long as Janssen continues to make reasonably diligent efforts to make each delivery under this Project Agreement.

Section V.5 Comptroller General Access to Records

To the extent that the total Government payment under this Project Agreement exceeds \$5,000,000, the Comptroller General, at its discretion, shall have access to and the right to examine records relevant to the work hereunder of any Consortium Member participating in the performance of this Project Agreement for a period of three (3) years after final payment is made. This requirement shall not apply with respect to any Consortium Member that participates in the performance of the Project Agreement that has not entered into any other Project Agreement (contract, grant, cooperative agreement, or "other transaction") that provides for access by a Government entity in the year prior to the date of this Project Agreement. This paragraph only applies to any record that was created or maintained in the ordinary course of business or pursuant to a provision of law in the performance of the Project Agreement.

Article VI. Disputes

A. General

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

B. Dispute Resolution Procedures

1. Any claim or dispute between the Government and Janssen concerning questions of fact or law arising from or in connection with this Project Agreement, and, whether or not involving an alleged breach of this Project Agreement, shall be raised and resolved under this Article.
2. Whenever legal disputes or claims arise, the Parties shall attempt to resolve the issue(s) by discussion and come to mutual agreement on a resolution as soon as practicable. In no event shall a dispute, disagreement or misunderstanding that arose more than three (3) months prior to the notification made under sub-section B.3 of this article constitute the basis for relief under this article unless one level above the AO, in the interests of justice, waives this requirement.
3. Failing resolution by mutual agreement, the aggrieved Party shall document the dispute, disagreement, or misunderstanding by notifying the other Party (through the AO or Janssen's POC, as the case may be) in writing of the relevant facts, identifying unresolved issues, and specifying the clarification or remedy sought. Within five (5) working days after providing notice to the other Party, the aggrieved Party may, in writing, request a joint decision by the ACC-NJ Division Chief for Emerging Technologies and senior executive appointed by Janssen. The other Party shall submit a written response on the matter(s) in dispute within thirty (30) calendar days after being notified that a decision has been requested. The Division Chief and the Recipient

senior executive shall conduct a review of the matter(s) in dispute and attempt to render a mutually agreeable decision in writing within thirty (30) calendar days of receipt of such written position. Any such joint decision is final and binding.

4. In the absence of a joint decision, upon written request to the ACC-NJ Associate Director made within thirty (30) calendar days of the expiration of the time for a decision under sub-section B.3 above, the dispute shall be further reviewed. The Associate Director may elect to conduct this review personally or through a designee or jointly with a senior executive appointed by Janssen. Following the review, the Associate Director or designee will resolve the issue(s) and notify the Parties in writing. This decision may be appealed to any federal court of competent jurisdiction.
5. Notwithstanding any other provisions of this Article, the Parties agree that Janssen shall have the right to pursue any contract dispute arising under this Project Agreement in any federal court of competent jurisdiction, including the appropriate Court of Appeals, or the Supreme Court, at any time without any administrative exhaustion requirements, and the timing requirements described above will not limit any claim in such tribunals. For the avoidance of doubt, the Parties agree that this Project Agreement satisfies all elements of an agreement.

C. Limitation of Damages

Claims for damages of any nature whatsoever pursued under this Project Agreement shall be limited to direct damages only up to the aggregate amount of Government funding obligated as of the time the dispute arises, except with respect to violations of the confidentiality, data rights, intellectual property, or PREP Act provisions of this Project Agreement.

Article VII. Confidential Information

Section VII.1 Authorized Disclosure

The Receiving Party shall not directly or indirectly, divulge or reveal to any person or entity any Confidential Information of another Party without the Disclosing Party's prior written consent, or use such Confidential Information except as permitted under this Project Agreement. Confidential Information shall be subject to the same prohibitions on disclosure as provided for under FAR Part 24.202. Further, any reproduction of Confidential Information or portions thereof that is disseminated within the Government, CMF, or Janssen, shall be shared strictly on a need to know basis for the purposes of this Project Agreement and is subject to the restrictions of this provision. In addition to the above, Confidential Information is subject to the protections of the Trade Secrets Act as well as any other remedies available under this Project Agreement or the law.

Section VII.2 Exclusions

Such obligation of confidentiality shall not apply to information which the Receiving Party can demonstrate through competent evidence: (i) was at the time of disclosure in the public domain; (ii) has come into the public domain after disclosure through no breach of this contract; (iii) was known to the Receiving Party prior to disclosure thereof by the Disclosing Party; (iv) was lawfully disclosed to the Receiving Party by a Third Party which was not under an obligation of confidence to the Disclosing Party with respect thereto; or (v) was approved for public release by prior written permission of the Disclosing Party.

Section VII.3 Term

The obligations of the Receiving Party under this Article shall continue for a period of seven (7) years from conveyance of the Confidential Information.

Article VIII. Publication and Academic Rights

Section VIII.1 Use of Information.

Janssen shall have the right to publish or otherwise disclose information and/or data generated under the Project. Janssen shall include an appropriate acknowledgement of the funding of the Project by the Government in any publication. Notwithstanding the above, the Parties shall not be deemed authorized by this paragraph, alone, to disclose any Confidential Information of another Party to this Project Agreement.

Section VIII.2 Publication or Public Disclosure of Data

Review and Approval of Data for Public Release.

(1) At least 30 days prior to the scheduled release date, Janssen shall submit to the AOR a copy of the Data to be released.

(2) An acknowledgment similar to the following shall be required in any publication of any Data, based or developed under this Project Agreement:

“Effort funded in part by the U.S. Government under P00081 Modification to Other Transaction Number W15QKN-16-9-1002 between the Janssen Pharmaceuticals, Inc., MCDC, and the Government.”

(3) Parties to this Project Agreement are also responsible for assuring that every publication of material funded under this project contains the following disclaimer:

“The views and conclusions contained herein are those of the authors and do not be represent the official policies or endorsements, either expressed or implied, of the U.S. Government.”

Article IX. Patent Rights

Section IX.1 Background Intellectual Property Disclosures

Janssen asserts full title to all background intellectual property relevant to its performance of this statement of work and listed at Attachment 1. Janssen hereby conveys a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States to the "Licensed Patents" throughout the world for the prevention, diagnosis and treatment of COVID-19 caused by Severe Respiratory Syndrome-Coronavirus-2 (SARS CoV-2). "Licensed Patents" means US Provisional Patent Application Serial Nos. (b) (4)

as well as any and all patent applications and patents (including any counterparts, PCT's, national stage applications, divisionals, continuations, or the like thereof, and any extensions thereof), wherever filed in the world, that claim priority to US Patent Application Serial No. (b) (4)

The Parties agree that nothing in this Project Agreement will otherwise alter the existing patent rights of the Parties unless expressly agreed upon.

Section IX.2 Allocation of Principle Rights

If Janssen elects to retain title to a Subject Invention, Janssen or its designee shall retain the entire right, title, and interest throughout the world to each Subject Invention developed under this Project Agreement consistent with the provisions of this Article and 35 U.S.C § 202 subject to the retention by the Government of a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced on behalf of the United States any Subject Invention. The license retained by the Government does not include the right to use or allow others to use the Subject Invention for commercial purposes.

Section IX.3 Invention Disclosure, Election of Title, and Filing of Patent Application

- a. Janssen shall disclose each Subject Invention to the Government within two (2) months of the Subject Invention being disclosed in writing to the person responsible for Janssen patent matters. The Subject Invention shall be disclosed in writing to the Government, via appropriate filings in the iEdison system or its replacement/alternative system, with a copy of said reporting being sent to JPEO-CBRND. Further, Janssen shall elect in writing whether or not to retain title to any such invention by notifying the Government within 6 months of disclosure to the Government.
- b. Where publication, sale, or public use has initiated the one (1)-year statutory period wherein valid patent protection can still be obtained in the United States,

- the period for such notice of election may be shortened by the Government to a date that is no more than sixty (60) calendar days prior to the end of the statutory period.
- c. If electing title, Janssen will file its initial patent application on a Subject Invention to which it elects to retain title within one year after election of title, or, if earlier, prior to the end of the statutory period wherein valid patent protection can be obtained in the United States after a publication, or sale, or public use.
 - d. Foreign Patent Filing Requirements: Janssen may elect to file corresponding patent applications in additional countries outside the U.S. (including but not limited to the European Patent Office and the Patent Cooperation Treaty) at its discretion. To enable the Government to protect patent rights in Subject Inventions in all potential countries, Janssen shall inform the Government of which countries Janssen shall NOT file patents applications in for all elected Subject Inventions at least 3 months prior to the filing deadline therein (e.g., in PCT national stage applications, at least 3 months prior to the PCT national stage filing deadline). Janssen understands that, in case the Government decides to file in a particular country following a notice provided under the preceding sentence, all ownership and interest in Subject Inventions in said countries (where Janssen shall not file patent applications in) are thereby automatically conveyed to the Government, and Janssen agrees to timely execute any documentation required to effectuate this conveyance, so as to enable the Government to perfect patent filing in said countries, always subject to the license described in Article IX, Section 5(a).
 - e. If Janssen does not elect title via the process described above, or determines that neither it nor its designee intends to file any patent applications on a Subject Invention, Janssen shall notify the Government, in writing, within 6 months of disclosure of such Subject Invention to the Government. Janssen agrees, in such case, to permit the Government to elect title to said Subject Invention, and thereby have full rights and ownership therein, at least 3 months PRIOR to the end of the one (1)-year statutory period wherein valid patent protection can still be obtained in the United States after any publication, sale, or public use.
 - f. In addition to the reporting required above, Janssen shall identify Subject Inventions in an annual report and the final report, which shall be in sufficiently complete technical detail to convey a clear understanding to the extent known at the time of the disclosure, of the nature, purpose, operation, and the physical, chemical, biological, or electrical characteristics of the Subject Invention.
 - g. Neither Party will publicly disclose any Subject Invention until a patent application describing the Subject Invention is filed, or a reasonable period of time has passed in the event that a patent application is not filed, in order to protect the patentability of the invention pursuant to 35 U.S.C. § 205.

Section IX.4 Conditions When the Government May Obtain Title

Upon JPEO-CBRND's written request, Janssen shall convey title to the Government:

- a. Of any Subject Invention, if Janssen fails to disclose the Subject Invention or elects not to retain title to the Subject Invention within the times specified in Article IX, Section 3(a) and (b), the Government may request title for a period of up to 60 calendar days after learning of the failure of Janssen to disclose within the specified times. For the avoidance of doubt, disclosure under this paragraph shall be deemed to have occurred at the time of Janssen's notification to JPEO-CBRND of a Subject Invention regardless of whether such disclosure meets the standards set forth in Article IX, Section 3(a) above.
- b. Of a patent application or patent that claims a Subject Invention, as the case may be, in any country in which Janssen decides not to continue the prosecution of such patent application, or to pay the maintenance fees on or defend in reexamination or opposition proceedings such a patent.

Section IX.5 Minimum Rights to Janssen's Consortium and Protection of Janssen's Consortium's Right to File.

- a. Janssen shall retain a nonexclusive, royalty-free license throughout the world in each Subject Invention to which JPEO-CBRND obtains title under Article IX, Section 8. The Janssen license extends to the Janssen's Affiliates, and includes the right to grant licenses of the same scope to the extent that Janssen was legally obligated to do so at the time the Project Agreement was awarded or at the time of the Subject Invention was invented. The license is transferable only with the approval of JPEO-CBRND, except when transferred to the successor of that part of the business to which the Subject Invention pertains. JPEO-CBRND approval for license transfer shall not be unreasonably withheld.
- b. The Janssen license may be revoked or modified by the Government to the extent necessary to achieve expeditious Practical Application of the Subject Invention pursuant to an application for an exclusive or non-exclusive license submitted consistent with appropriate provisions at 37 CFR Part 404.
- c. Before modification of the license, JPEO-CBRND shall furnish Janssen a written notice of its intention to revoke or modify the license, and Janssen shall be allowed thirty (30) calendar days (or such other time as may be authorized for good cause shown) after the notice to show cause why the license should not be modified.

Section IX.6 Action to Protect JPEO-CBRND's Interest

- a. Janssen agrees to execute or to have executed and promptly deliver to JPEO-CBRND all instruments necessary to (i) establish or confirm the rights JPEO-CBRND has throughout the world in those Subject Inventions to which Janssen elects to retain title, and (ii) convey title to JPEO-CBRND when requested under Section 4 of this Article IX and to enable JPEO-CBRND to obtain patent protection throughout the world in that Subject Invention.
- b. Janssen agrees to require, by written agreement, its employees, other than clerical and non-technical employees, to disclose promptly in writing, to personnel identified as responsible for the administration of patent matters and in a format suggested by Janssen, each Subject Invention in order that Janssen can comply with the disclosure provisions of Section 3 of this Article IX. Janssen shall instruct employees, through employee agreements or other suitable educational programs, on the importance of reporting Subject Inventions in sufficient time to permit the filing of patent applications prior to U.S. or foreign statutory bars.
- c. Janssen shall notify JPEO-CBRND of any decisions not to continue the prosecution of a patent application claiming a Subject Invention, pay maintenance fees on a patent claiming a Subject Invention, or defend in a reexamination or opposition proceedings on a patent claiming a Subject Invention, in any country, not less than sixty (60) calendar days before the expiration of the response period required by the relevant patent office.
- d. Janssen shall include, within the specification of any United States patent application and any patent issuing thereon claiming a Subject Invention, the following statement: "This invention was made with Government support under Agreement [W15QKN-19-6-1002, 2011-004], awarded by JPEO-CBRND. JPEO-CBRND has certain rights in the invention."

Section IX.7 Reporting on Utilization of Subject Inventions

- a. Janssen shall submit, during the term of the Project Agreement, an annual report on the utilization of Subject Inventions or on efforts at obtaining such utilization that are being made by or on behalf of Janssen or its licensees or assignees. Such reports will include information regarding the status of development, date of first commercial sale or use, and such other data and information as the agency may reasonably specify. Janssen shall provide additional reports as may be requested by JPEO-CBRND in connection with any march-in proceedings undertaken by the Government in accordance with Article IX, Section 8 of this Project Agreement. Consistent with 35 U.S.C. § 202(c) (5), JPEO-CBRND agrees it shall not disclose such information to persons outside JPEO-CBRND without permission of Janssen.

- b. All required reporting shall be submitted to the AO and AOR.
- c. Where the Subject Invention is a drug or a vaccine, or a method of manufacturing, administering or using a drug or vaccine, Practical Application in view of the March-in Rights in Article IX, Section 8 below is achieved with respect to:
 - i. such drug or vaccine, if a Phase IIa clinical study is completed that studies such drug or vaccine; or
 - ii. such method of use, if the method of use is employed in manufacture, administration or use of such drug or vaccine in connection with a Phase IIa clinical study.
- d. Failure to complete a Phase IIa clinical study does not per se constitute a failure to achieve Practical Application.

Section IX.8 March-in Rights

Janssen agrees that, with respect to any Subject Invention in which it has acquired title, the Government may request Janssen, an assignee, or exclusive licensee of a Subject Invention to grant a non-exclusive license, within the Field of use to a responsible US-based third party, upon terms that are reasonable under the circumstances. If Janssen, assignee, or exclusive licensee initially refuses such a request, the Government may obligate Janssen to grant such a license subject to Article IX, Section 8(c) below if the Government determines that:

- a. Such action is necessary because Janssen or assignee has not taken steps (or is not expected to take within a reasonable time), consistent with the intent of this Project Agreement, to achieve Practical Application of the Subject Invention; or
- b. Such action is necessary to alleviate the following urgent health or safety needs not reasonably satisfied by the contractor that affect the United States and that are not reasonably satisfied by Janssen, assignee, or their licensees:
 - i. declaration for Public Health Emergency by the Secretary of the Government;
 - ii. determination that there is a significant potential for a public Health emergency that has a significant potential to affect the national security or public health of U.S. citizens as determined by the Secretary of the Government; or
 - iii. declaration by WHO Director General of a public health emergency of

international concern.

- c. Where the circumstances described in Article IX, Section 8(a) and or (b) are met, Janssen will act promptly to negotiate in good faith with the responsible US-based third party a non-exclusive license on terms that are reasonable under the circumstances under the SI Intellectual Property Rights it controls at the time to make, have made, use, sell, offer for sale and import the relevant Subject Invention in the Field to the extent necessary to alleviate the public health emergency in the United States.

Section IX.9 Background Information

Janssen shall retain the entire right, title, and interest throughout the world to each such Invention and Patent that Janssen has brought to the Prototype Project issued under this Project Agreement/Statement of Work and the Government shall not have any rights under this Project Agreement/Statement of Work to such Inventions and Patents unless identified herein. Attachment 1 to the Project Agreement contains non-exhaustive overview of Janssen's Background Patents, patent applications and Inventions at the Effective Date. Table 10-1 in Article X "Data Rights" provides a non-exhaustive overview of Data Rights, information and Technical Data that Janssen will bring to the Project Agreement at the Effective Date. The Government shall have no rights to these Background Inventions, Patents, information and Technical Data and any further Background Inventions, Patents, information and Technical Data identified during the Term of the Project Agreement or afterwards.

Article X. Data Rights

Table 10-1: Janssen Background Information, Data Rights and Technical Data

<i>Technical Data to be Furnished with Restrictions</i>	<i>Basis for Assertion</i>	<i>Asserted Rights Category</i>	<i>Name of Person Asserting Restrictions</i>
(b) (4)		A	Janssen
(b) (4)		A	Janssen
(b) (4)		A	Janssen
(b) (4)		A	Janssen
(b) (4)		A	Janssen

Technical Data to be Furnished with Restrictions	Basis for Assertion	Asserted Rights Category	Name of Person Asserting Restrictions
(b) (4)		A	Janssen
(b) (4)		A	Janssen
(b) (4)		A	Janssen
(b) (4)		A	Janssen
(b) (4)		A	Janssen
(b) (4)		A	Janssen
(b) (4)		A	Janssen

Section X.1 Data Categories

Article XI of the Agreement, is hereby superseded by the following terms and conditions:

There are two (2) categories of Data or other information established under this Project Agreement as listed below.

- a. Category A is Data or other information to which Janssen retains all rights. Category A Data shall include, but not be limited to:
 - i. Data as defined in the Project Agreement, background (i.e., pre-existing or generated outside the scope of this Project Agreement) information and Technical Data identified in Table 10-1 and Attachment 1 (background Patents, patent applications and Inventions), and any designs or other material provided by Janssen for this Project Agreement which was not developed in the performance of work under this project, and to which Janssen retains rights.
 - ii. The Parties hereby mutually agree that any information developed outside of this Project Agreement whether or not developed with any Government funding in whole or in part under a Government agreement, contract or subcontract shall have the rights negotiated under such prior agreement, contract or subcontract; the Government shall get no additional rights in such information.
- b. Category B is any Data developed exclusively with Government funds under this Project Agreement.
 - i. The Government will have Government Purpose Rights in Data developed exclusively with Government funds under this Project Agreement.
 - ii. The Government shall have unlimited rights in Data:
 - (a) Otherwise publicly available or that has been released or disclosed by Janssen without restrictions on further use, release or disclosure, other than a release or disclosure resulting from the sale, transfer, or other assignment of interest in the Data to another party or the sale or transfer of some or all of a business entity or its assets to another party;
 - (b) Data in which the Government has obtained unlimited rights under another Government contract or as a result of negotiations; or
 - (c) Data furnished to the Government, under this or any other

Government contract or subcontract thereunder, with—

1. government purpose rights or limited rights and the restrictive condition(s) has/have expired; or
 2. Government purpose rights and Janssen's exclusive right to use such Data for commercial purposes under such contract or subcontract has expired.
- iii. However, any Data or other information developed outside of this OTA whether or not developed with any Government funding in whole or in part under a Government agreement, contract or subcontract shall have the rights negotiated under such prior agreement, contract or subcontract; the Government shall get no additional rights in such Data or other information.

Section X.2 Allocation of Principle Rights

- a. The Government shall have no rights to Category A Data or other information, but shall have rights to Deliverables as described in Table I-5.
- b. The Government will receive Government Purpose Rights in Data or other information exclusively funded by the Government and otherwise Limited Rights in any data delivered in the performance of the SOW. To the extent that the Parties mutually agree that there will be Data subject to Government Purpose Rights, Data subject to Government Purpose Rights may only be shared with parties outside the Government when such parties are subject to the non-disclosure agreement at DFARS 227.7103-7 with respect to the data or are receiving the data under a Government contract subject to DFARS 252.227-7025. Any delivered Data or other information which is part of a patent application claiming a Subject Invention will be subject to the disclosure and release restrictions set forth in Article X, Section 2 of this Project Agreement.
- c. Data or other information in any document which is a part of a patent application that would disclose a Subject Invention will be subject to Limited Rights until publication of patent application in accordance with Article X of this Project Agreement/Statement of Work.
- d. Janssen agrees to retain and maintain in good condition all Data necessary to achieve Practical Application of any Subject Invention in accordance with the Janssen's established record retention practices. In the event of exercise of the Government's March-in Rights as set forth under Article X, Janssen agrees, upon written request and with adequate additional support from the Government, as mutually agreed between the Parties, to deliver Data necessary to achieve Practical Application within one-hundred and twenty (120) calendar days from the date of the written request.

- e. Janssen's right to use Data is not restricted and includes the right under Janssen's established business policies to make public research data (especially human research data) by publication in the scientific literature, by making trial protocols, trial results summaries, and clinical studies reports publicly available, and by making trial patient-level data available for third-party analysis. The Government agrees that the materials, if any, being developed under this Project Agreement/Statement of Work are being developed for both civilian and military applications.

Section X.3 Identification and Disposition of Data

Janssen shall keep copies of all Data required by the FDA relevant to this Project Agreement for the time specified by the FDA and provide such Data to AO. The Government reserves the right to review any other Data determined by the Government to be relevant to this Project Agreement/Statement of Work subject to Limited Rights.

a. Marking of Data

Pursuant to section A above, any Data delivered under this Project Agreement/Statement of Work that is subject to Government Purpose Rights shall be marked with the following legend or similar:

"GOVERNMENT PURPOSE RIGHTS: The Government's right to use, modify, reproduce, perform, display or disclose this Data is restricted by P00081 Modification to the MCDC OTA No. W15QKN-16-9-1002 between the Government, ATI and Janssen, and those restrictions do not permit disclosure to any party outside the Government unless such disclosure is for government purposes and not facilitating commercial sale beyond the government. Any reproduction of this Data or portions thereof must be marked with this legend."

- b. Pursuant to section A above, any Data delivered under this Project Agreement/Statement of Work that is subject to Limited Rights shall be marked with the following legend or similar:

"LIMITED RIGHTS: The Government's right to use, modify, reproduce, perform, display or disclose this Data is restricted by P00081 Modification to the MCDC OTA No. W15QKN-16-9-1002 between the Government, ATI and Janssen, and those restrictions do not permit disclosure to any party outside the Government without prior agreement of Recipient. Any reproduction of this Data or portions thereof must be marked with this legend."

Article XI. Export Control

This term/condition is not applicable to this Project Agreement.

Article XII. Government Furnished Property

It is not anticipated that any Government furnished equipment, materials, information, or other property will be provided to Janssen nor will Janssen procure any property intended to be Government furnished under this Project Agreement.

Article XIII. Civil Rights Act

Reference back to Article XIV of the MCDC Base OTA No. W15QKN-16-9-1002.

Article XIV. Small Business Affiliation

This term/condition is not applicable to this Project Agreement.

Article XV. Antitrust

This term/condition is not applicable to this Project Agreement.

Article XVI. Security and Operations Security ("OPSEC")

To the extent that Janssen does not meet any requirements in this Article XVI or Attachment 2 at the time of award of this Project Agreement, Janssen will notify the Government and will have 180 days to work with the Government to develop a plan to which Parties agree to address such requirements, Janssen will be entitled to an equitable adjustment to account for costs associated with implementing the plan agreed to by the Parties.

The OPSEC provisions included in Attachment 2 are hereby incorporated into this Project Agreement.

All PAH shall comply with DFARS 252.204-7012 (Oct 2016): Safeguarding Covered Defense Information and Cyber Incident Reporting when applicable.

Covered Defense Information ("CDI") will be identified at the Project Agreement level. The MCDC Member shall comply with DFARS 252.204-7012 (Oct 2016): Safeguarding Covered Defense Information and Cyber Incident Reporting, which includes implementing on its covered contractor information systems the security requirements specified by DFARS 252.204-7012. Nothing in this paragraph shall be interpreted to foreclose the MCDC Member's right to seek alternate means of complying with the security requirements in National Institute of Standards and Technology ("NIST") Special Publication (SP) 800-171 (as contemplated in DFARS 252.204-7008 (Compliance with

Safeguarding Covered Defense Information Controls) (Oct 2016) and DFARS 252.204-7012 (Safeguarding Covered Defense Information and Cyber Incident Reporting (Oct 2016)).

(1) For all Project Agreements, the following statement shall be flowed to the MCDC member entities unless otherwise stated within the Project Agreements.

a) Classification guidance for requirement - "The security level for this agreement is UNCLASSIFIED."

Article XVII. Safety

This term/condition is not applicable to this Project Agreement.

Article XVIII. Representations and Warranties

Reference back to Article XIX of the MCDC Base OTA No. W15QKN-16-9-1002.

Section XVIII.1 Representations and Warranties of All Parties

Each Party to this Project Agreement represents and warrants to the other Parties that (1) it is free to enter into this Agreement; (2) in so doing, it will not violate any other agreement to which it is a party; and (3) it has taken all action necessary to authorize the execution and delivery of this Project Agreement and the performance of its obligations under this Project Agreement.

Section XVIII.2 Limitations

Except as expressly provided herein, no Party to this Project Agreement makes any warranty, express or implied, either in fact or by operation of law, by statute or otherwise, relating to (1) any research conducted under this Project Agreement, or (2) any invention conceived and/or reduced to practice under this Project Agreement, or (3) any other intellectual property developed under this Project Agreement or noninfringement, and EACH PARTY TO THIS PROJECT AGREEMENT SPECIFICALLY DISCLAIMS ANY IMPLIED WARRANTY OF MERCHANTABILITY OR WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE.

Article XIX. General Provisions

Section XIX.1 Fees

This term/condition is Not Applicable to this Project.

Section XIX.2 Waiver

Reference back to Article XXI, Section 2 of the MCDL Base OTA No. W15QKN-16-9-1002.

Section XIX.3 Section Headings

Reference back to Article XXI, Section 3 of the MCDL Base OTA No. W15QKN-16-9-1002.

Section XIX.4 Severability

If any provision of this Project 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 Project 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.

Section XIX.5 Excusable Delay

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 (an "Excusable Delay Event"). Examples of such circumstances are: authorized acts of the Government in its sovereign capacity (or failure to take reasonably expected acts), war, insurrection, freight embargos, fire, flood, or strikes. The Party asserting Excusable Delay as an excuse must take reasonable steps to minimize delay or damages caused by unforeseeable events. The Government may not identify any aspect of the COVID-19 pandemic as an Excusable Delay Event relieving it of its responsibilities under this Project Agreement.

Section XIX.6 Regulatory Rights

- a. The Parties understand and hereby acknowledge that BARDA OTA No. HHSO100201700018C ("BARDA OTA") governs Janssen's responsibilities and obligations with regards to IND activities regarding Janssen's Ad26.COVS vaccine, specifically, Work Package 6.14, "Regulatory Support" of the BARDA OTA. Under the BARDA OTA, Janssen leads regulatory activities with the FDA. Janssen manages all regulatory communications, documentation, and submissions with health authorities. Janssen provides BARDA with all communications and summaries thereof, both formal and informal, to or from FDA regarding the Investigational New Drug ("IND") activities regarding Janssen's Ad26.COVS vaccine and will invite the BARDA/JPEO-CBRND representatives to participate in any formal meetings between FDA and Janssen. Additionally, for this Project Agreement, Janssen will authorize BARDA to share information with the United States Department of Defense, JPEO-CBRND, as BARDA deems appropriate, in accordance with the Data Rights requirements of BARDA OTA No. HHSO100201700018C.
- b. The Parties also understand that PL-115-92 allows the DoD to request, and FDA to provide, assistance to expedite development and the FDA's review of products to diagnose, treat, or prevent serious or life-threatening diseases or conditions facing American military personnel. Janssen recognizes that only the DoD is authorized to invoke PL-115-92. If Janssen, the DoD, and BARDA agree that the circumstances exist under the BARDA OTA to warrant DoD's involvement, Janssen and BARDA may request DoD to utilize its authority under PL-115-92 to engage the FDA.

If DoD, in its sole discretion, determines that it will engage with the FDA, the Parties agree that DoD will only invoke this authority in order to assist or facilitate Janssen in obtaining the necessary FDA approvals or authorizations. Notwithstanding any other provision in this Project Agreement, the BARDA OTA, or PL-115-92, the Parties agree that DoD shall not use its authority to become a "sponsor," co-sponsor, or "applicant" as defined in the regulations cited in this Article. Further, the Parties hereby agree that any information provided to DoD by Janssen, to facilitate with the FDA under PL-115-92, will be provided with Limited Rights pursuant to the BARDA OTA.

- c. *Rights of Reference.* In the event that all of the conditions described in Article 19, Section 7(1) are met, Janssen will grant the Government a right of reference to any regulatory application submitted to the FDA in support of this Project Agreement/Statement of Work. Separately, upon the DoD's request, Janssen will grant the DoD a right of reference to any regulatory application submitted to the FDA in support of this Project Agreement/Statement of Work for the DoD's regulatory filings involving (a) the use of a product to treat or prevent COVID-19 or (b) one of the material threats identified in Attachment 3, in each case for which the DoD is identified as the filing sponsor. DoD may request a

right of reference to additional material threats identified by the Government under Section 319F-2(c)(2)(A)(ii) of the Public Health Service Act, and Janssen may consent to provide such a right of reference with the agreement that its consent will not be unreasonably withheld. For clarity, the rights of reference identified in this paragraph will only authorize the FDA to cross-reference regulatory applications and will not provide the DoD or any other party with a right to access or review any such applications or information included in such applications.

Section XIX.7 Failure to Provide Prototype Product

1. In recognition of the Government's need to provide sufficient quantities of a safe and effective Prototype Product to protect the United States population, the Government shall have the remedy described in this section to ensure sufficient supply of the Prototype Product to meet the needs of the public health or national security when the following conditions are met:

- a. Janssen gives written notice (which it hereby agrees to do) to the Government no later than 15 business days following:
 - i. except as permitted under Article I, Section 3 or in connection with a termination of this Project Agreement under Article II, Section 2 above, any formal management decision to terminate manufacturing of the Prototype Product prior to delivery of 100 million Regimens of the Prototype Product to USG; or
 - ii. except as permitted under Article I, Section 3 or in connection with a termination of this Project Agreement under Article II, Section 2 above, any formal management decision to discontinue sale of the Prototype Product to the Government prior to delivery of 100 million Regimens of the Prototype Product to USG; or
 - iii. any filing that anticipates Federal bankruptcy protection of Janssen prior to the delivery of 100 million Regimens of the Prototype Product; and
- b. Janssen
 - i. is authorized to supply the Prototype Product under an Emergency Use Authorization under §564 of the FD&C Act; or
 - ii. has an FDA approval to market the Prototype Product in the U.S. under the provisions of §351(a) of the Public Health Service Act (PHSA).

2. If both conditions listed in subsection (1) occur, Janssen, during the emergency pandemic for COVID-19 issued under §319 of the PHSA, upon the written request of the Government, will act promptly to license a Third-Party Licensee all Janssen Prototype Product Rights on reasonable terms for the continuation and/or initiation of manufacturing of the Prototype Project at the Government's expense.

3. This Article will survive the acquisition or merger of Janssen with a third party. This Article will survive the expiration of this Project Agreement unless the Project Agreement was terminated under Article II, Section 2(a).

Section XIX.8 Radioactive Materials

This term/condition is not applicable to this Project Agreement.

Section XIX.9 Recombinant DNA

This term/condition is not applicable to this Project Agreement.

Section XIX.10 Required Compliance for Use of Laboratory Animals

This term/condition is not applicable to this Project Agreement.

Section XIX.11 Required Compliance for Use of Human Subjects

This term/condition is not applicable to this Project Agreement.

Section XIX.12 Required Compliance for use of Human Anatomical Substances

This term/condition is not applicable to this Project Agreement.

Section XIX.13 Compliance with Good Manufacturing Processes

The cGMP (21 CFR 210-211) will be the standard applied for manufacturing, processing and packing of any products to be administered to human subjects under this Project Agreement subject to any applicable guidance from, or enforcement discretion exercised by, the FDA in connection with COVID-19 subject to any applicable guidance from, or enforcement discretion exercised by, the FDA in connection with COVID-19.

If at any time during the life of this contract, the Recipient fails to comply with cGMP in the manufacturing, processing and packaging of the products subject to the exception noted above and such failure results in a material adverse effect on the safety, purity or potency of the products (a material failure) as identified by Center for Biologics Evaluation and Research and Center for Drug Evaluation and Research, the Recipient shall have thirty (30) calendar days from the time such

material failure is identified to cure such material failure. If the Recipient fails to take such an action within the thirty (30) calendar day period, then the contract may be terminated.

The Recipient agrees to comply with cGMP guidelines (21 CFR Parts 210-211,600) for manufacturing, processing and packing of drugs, chemicals, biological, and reagents subject to any applicable guidance from, or enforcement discretion exercised by, the FDA in connection with COVID-19.

The Recipient agrees to advise the AO and AOR promptly of any relocation of their prime manufacturing facility or the relocation of any sub consortium's facility during the term of this Project Agreement. The Recipient also agrees to advise the AO and AOR immediately if at any time during the term of this Project Agreement, the items under this OTA fail to comply with cGMP guidelines and/or the facility receives a negative FDA Quality Assurance Evaluation (Form 483).

Section XIX.14 Registration with Select Agent Program

This term/condition is not applicable to this Project Agreement.

Section XIX.15 Duty Free Entry

Reference back to Article XXI, Section 14 of the MCDC Base OTA No. W15QKN-16-9-1002.

Article XX. Assignment of Agency

Neither this Project Agreement nor any rights or obligations of any Party hereunder shall be assigned or otherwise transferred by any Party without the prior written consent of the other Parties, except that Janssen may assign to an Affiliate or to a third party to whom it transfers the portion of its business applicable to this Project Agreement, in each case, without prior written consent.

Article XXI. Order of Precedence

In the event of any inconsistency between the general terms of this Project Agreement and the Agreement, the inconsistency shall be resolved by giving precedence in the following order: (1) the Scope/Statement of Work of the Project Agreement; (2) Attachments to the Project Agreement; (3) the Project Agreement terms and conditions; (4) documentation (including but not limited to Janssen's proposal selected for funding by the Government); (5) the general terms and conditions of the Agreement. In any event, specifically negotiated Project Agreement terms will govern over general terms of the Agreement.

The Parties mutually agree that any terms and conditions that have been identified with the following statement **"This term/condition is Not Applicable to this Project**

Agreement” shall have no effect and are expressly excluded from the MCD C Base OTA No. W15QKN-16-9-1002. The terms and conditions in the MCD C Base OTA No. W15QKN-16-9-1002, that have been changed within this Project Agreement, are hereby superseded by the language in this Project Agreement. As such, those sections from the MCD C Base OTA No. W15QKN-16-9-1002 shall no longer remain operative with regards to this Project Agreement/Statement of Work. Any terms and conditions that have not been changed or have not been identified with the above statement remain unchanged and in full force and effect.

Article XXII. Execution

This Project Agreement constitutes the entire agreement of the Parties and supersedes all prior and contemporaneous agreements, understandings, negotiations and discussions among the Parties, whether oral or written, with respect to the subject matter hereof. This Project Agreement may be revised only by written consent of Janssen and the AO. This Project Agreement, or modifications thereto, may be executed in counterparts each of which shall be deemed as original, but all of which taken together shall constitute one and the same instrument.

Article XXIII. Antibribery and Anti-Corruption

The Government acknowledges that it has received and read Recipient's 'Prevention of Corruption - Third Party Guidelines.' Each Party agrees to perform its obligations under this Project Agreement in accordance with the applicable anti-bribery and anti-corruption laws of the territory in which such Party conducts business with the other Party as set forth herein. Each Party shall be entitled to exercise its termination right, under and in accordance with the terms of this Project Agreement, to terminate this Project Agreement immediately on written notice to the other Party, if the other Party fails to perform its material obligations in accordance with this Article XXIII.

Article XXIV. Inspection, Acceptance, & Delivery

A. Acceptance

- Upon acceptance by the AOR of any lot of vaccine under this Project Agreement and confirmation from the AO, title to such vaccine will transfer upon (a) delivery of DP to vendor-managed inventory (“VMI”), or delivery to a site designated by the Government, as initially applicable, and (b) the Government’s corresponding written acceptance of each delivery. Storage as VMI may only take place up to twelve months after (b) (4), (b) (2) [REDACTED]
[REDACTED]
[REDACTED]
- Any deviations, out of specification (“OOS”) results, or other product issues, shall be reported to the USG within 3 calendar days after initial delivery.

- When held in VMI, these materials should be maintained in Janssen's or its designated representative's quality and inventory systems. Delivered Regimens are intended for clinical use or use under Emergency Use Authorization or a BLA. Product held in VMI is subject to the following requirements:
 - Provide temperature controlled storage at the manufacturer's site approved by the Government, according to cGMP and product specifications.
 - Store Project Agreement products physically segregated from other products.
 - Ensure proper labeling of stored materials as USG property.
 - Execute stability testing of stored material in a manner consistent with the stability testing plan approved by the Government. Report interim data and results to the Government on a monthly basis.
 - Appropriately identify reserve samples that are representative of drug product shall be retained. The reserve samples consist of at least twice the quantity necessary for all tests required to determine whether the drug product meets its established specifications including a minimum of 60 months of stability testing.
 - Provide the Government access to review the security systems in place and request updates as needed.
 - Include in monthly report inventory for drug product (number of vials), including inventory quantity changes, current quantity, storage facility/location, manufacturing date, latest stability result for potency, date of next expected stability result and the current expiration date (if applicable).
 - Ensure that material being relocated for Janssen's convenience is adequately insured at no cost to the government and with AO approval.
 - Conduct testing necessary to ensure continued use of the stored material for pandemic response.
 - Make appropriate updates to the regulatory documentation supporting the continued use of the stored material for pandemic response.
 - If using a storage site, provide the quality agreement, specify the location and terms of the storage contract and receive approval by the Government.

- Notification must be made to the AO and AOR at least 10 calendar days prior to initial delivery. Exceptions are permitted if approved by the AO.
- The Government shall accept product that conforms to contract requirements based on Certificates of Analysis and certificate(s) of cGMP conformity provided by Janssen. The Government's acceptance of product will be deemed to have occurred if the Government does not provide written notice of acceptance or rejection within fourteen (14) calendar days of Janssen's provision of all applicable certificates.
- Upon receipt of the provided certificates and any inspection that was timely requested (physical or representative, i.e., pictures), the AOR will review and recommend acceptance or rejection; the AO will correspondingly notify Janssen of acceptance or rejection.
- Upon delivery of product, notification of delivery quantities and any movement must be made to the AOR and Government representatives.
- Upon request before storage in VMI or, if storage was initially ordered, after storage in VMI, unless otherwise mutually agreed upon by the Parties, DP shall be shipped, trackable by GPS, to the Government-designated sites within the continental United States.
- Janssen will retain physical risk of loss for all product stored as VMI until subsequent delivery to the Government at the Government-designated site. If product is initially delivered to a Government site instead of VMI, risk of loss will transfer upon delivery and acceptance at the Government-designated site. Notwithstanding either of the foregoing sentences, Janssen shall not be liable for loss of or damage to supplies caused by the negligence of officers, agents, or employees of the Government acting within the scope of their employment.
- Janssen will notify the AO and AOR of any storage or quality deviation for product held in VMI, within 3 calendar days.
- To the extent that Janssen is responsible for the correction, repair or replacement of Government property held in VMI and replacement upon loss or damage is feasible, the Government will accept replacement of such property.
- Vendor-managed storage of product manufactured under this Project Agreement is supported for up to twelve months after (b) (4), (b) (2) and, as such, the Government must either (a) take possession on or before the end of this period and provide Janssen with disposition instructions in sufficient time to transfer physical material from Janssen by this date or (b) bilaterally modify

this Project Agreement to extend the period of vendor management of storage prior to this date.

- The Government understands that prices identified in this contract include insurance costs applicable to material that will become Government property, including product stored as VMI.
- Janssen cannot reclaim title to product upon acceptance by the Government. Prior to expiration or termination of this Project Agreement, the Government may affect final distribution of any vaccines remaining in storage by any one or combination of the following methods:
 - The Government may elect to require shipment of the vaccine to US Government facilities.
 - The Government may direct Janssen to destroy all quantities remaining in storage. In this case, a letter of disposition will be provided to the USG.

B. Inspection

USG right to inspect product: The AO and/or the AOR may perform inspection of materials and services. Inspections of material created under this Project Agreement may be made by a duly authorized Government representative, and with reasonable notice (i.e., not less than 24 hours).

Article XXV. Foreign Access to Technology

(a) Except as authorized by the Office of Foreign Assets Control ("OFAC") in the Department of the Treasury, the Contractor shall not acquire, for use in the performance of this contract, any supplies or services if any proclamation, Executive order, or statute administered by OFAC, or if OFAC's implementing regulations at 31 CFR chapter V, would prohibit such a transaction by a person subject to the jurisdiction of the United States.

(b) Except as authorized by OFAC, most transactions involving Cuba, Iran, and Sudan are prohibited, as are most imports from Burma or North Korea, into the United States or its outlying areas. Lists of entities and individuals subject to economic sanctions are included in OFAC's List of Specially Designated Nationals and Blocked Persons at <http://www.treas.gov/offices/enforcement/ofac/sdn/>. More information about these restrictions, as well as updates, is available in the OFAC's regulations at 31 CFR chapter V and/or on OFAC's website at <http://www.treas.gov/offices/enforcement/ofac>.

(c) The Contractor shall insert this clause, including this paragraph (c), in all subcontracts.

Article XXVI. Government Observer in Recipient Facility

With seven (7) days advance notice to the Recipient in writing from the AO, the Government may place an observer in a Recipient facility that is being used for work hereunder, who shall be subject to Recipient's policies and procedures regarding security and facility access at all times while in the Recipient's facility and who shall limit its activities to observing work related to this Project Agreement. As determined by federal law and as required under this Project Agreement/Statement of Work, no Government representative shall publish, divulge, disclose or make known in any manner, or to any extent not authorized by law, any information disclosed to that person in the course of employment or official duties performed while stationed in a Recipient facility.

Article XXVII. Reporting Matters Involving Fraud, Waste and Abuse

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in ASPR funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll-free number is 1-800-HHS-TIPS (1-800-447-8477). All telephone calls will be handled confidentially. The e-mail address is Htips@os.dhs.gov and the mailing address is:

Office of Inspector General
Department of
Health and Human
Services TIPS
HOTLINE
P.O. Box 23489
Washington, D.C. 20026

Article XXVIII. Prohibition on Contractor Involvement with Terrorist Activities

The Recipient acknowledges that U.S. Executive Orders and Laws, including but not limited to E.O.13224 and P.L. 107-56, prohibit transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. It is the legal responsibility of the Recipient to ensure compliance with these Executive Orders and Laws. This clause must be included in all subcontracts issued under this Project Agreement.

Article XXIX. Survival

Articles IV (PREP Act); V (Payment); VI, Sections (B) & (C) (Disputes and Limitations on Damages); VII (Confidential Information), IX (Patent Rights), X (Data Rights) and this Article XXIX shall survive the termination provisions in Article II, Section 2.

Section XXIX.1 Close-out Procedure

If the Government funds an individual Project Agreement and then subsequently terminates the agreement or the requirements of the Project Agreement are met, the following closeout procedures apply:

(a) Definitions.

- (i) "Closeout" – the process by which the Government and CMF determine that all applicable administrative actions and all required work have been completed by Janssen.
- (ii) "Date of Completion" – the date on which all work is completed or the date on an amendment thereto on which the period of performance ends.

(b) Upon request, the Government shall make prompt payments to Janssen through the CMF for outstanding payments and reimbursements under the Project Agreement being closed out.

(c) Janssen shall immediately refund any balance of unobligated (unencumbered) cash that the CMF has paid and that is not authorized to be retained by Janssen for use in the performance of the Project Agreement.

(d) The CMF shall obtain from Janssen within 180 calendar days after the date of completion of an Project Agreement all financial, performance, and other reports required as a condition of the Project Agreement. The CMF may grant extensions when requested by Janssen.

(e) Reserved.

(f) Quick close-out procedures similar to FAR 42.708 shall be followed.

(g) Janssen shall account for any property received from the Government.

ATTACHMENT 1:**Janssen's Background Patents, Patent Applications and Inventions****Listed Janssen Background Intellectual Property and Technical Data**

Attachment 1 comprises a table with the full list of pending and granted patents in the patent families listed below that, to the best of Janssen's knowledge, is accurate as of July 9, 2020. Janssen makes no representations or warranties with regards to the accuracy or completeness of that information. The Parties mutually agree that Janssen is not obligated to maintain the currency or accuracy of the information provided in the table.

Certain patent applications / patents on this list are registered at the patent office with Crucell Holland B.V. as the applicant. Crucell Holland B.V. was acquired by Johnson & Johnson in 2011 and subsequently changed its name to Janssen Vaccines & Prevention in 2016.

Certain patents on this list are owned by (b) (4) Janssen holds a license to these patents.

COVID Vaccination and Dosage Regimen:

Janssen has filed patent application(s), or is the assignee or licensee of pending patent applications including those listed below which contain(s) claims that are related to COVID Vaccines and Dosage regimens

- All patent applications and/or resulting patents (including any foreign counterparts, divisionals, continuations, or the like thereof, and any extensions thereof) that include a priority claim to (b) (4)

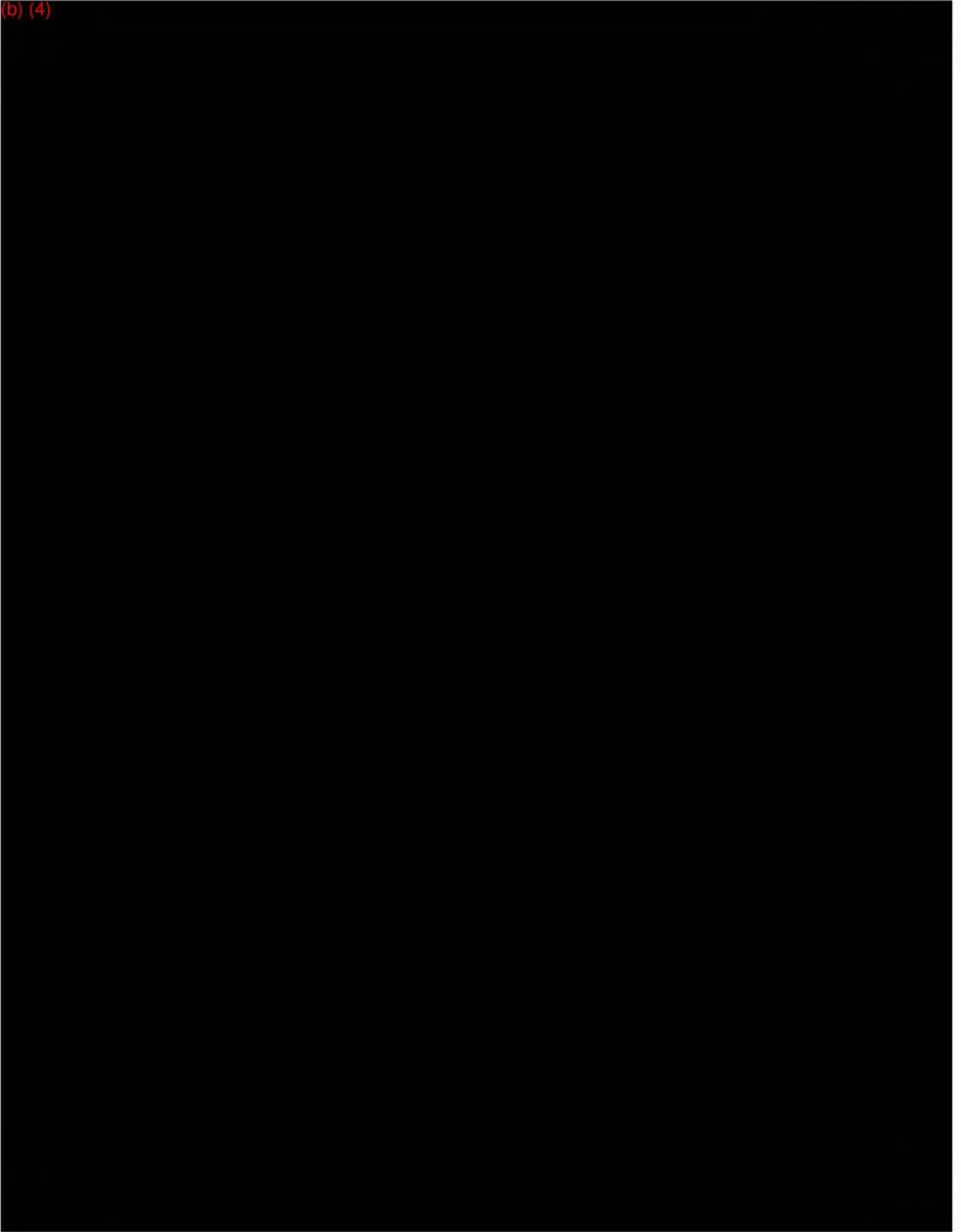
PER.C6® Technology and/or AdVac® Technology:

Janssen has filed patent application(s), or is the assignee or licensee of pending patent applications and/or issued patent(s), including those listed below which contain(s) claims that are related to PER.C6® technology and/or AdVac® technology.

(b) (4)



(b) (4)



(b) (4)

Table X: Janssen Assertion of Data Rights Technical Data

Technical Data to be Furnished With Restrictions	Basis for Assertion	Asserted Rights Category	Name of Person Asserting Restrictions
(b) (4)		A	Janssen
(b) (4)		A	Janssen
(b) (4)		A	Janssen
(b) (4)		A	Janssen
(b) (4)		A	Janssen
(b) (4)		A	Janssen
(b) (4)		A	Janssen
(b) (4)		A	Janssen
(b) (4)		A	Janssen
(b) (4)		A	Janssen

<i>Technical Data to be Furnished With Restrictions</i>	<i>Basis for Assertion</i>	<i>Asserted Rights Category</i>	<i>Name of Person Asserting Restrictions</i>
(b) (4) [REDACTED]	[REDACTED]	A	Janssen
(b) (4) [REDACTED]	[REDACTED]	A	Janssen
(b) (4) [REDACTED]	[REDACTED]	A	Janssen

Table: List of pending and granted background patents as of July 9, 2020.

[illegible]

MULTI-DOD-ARMY-20-2554, 20-2562-A-000079

[illegible]

[illegible]

MULTI-DOD-ARMY-20-2554, 20-2562-A-000082

[illegible]

MULTI-DOD-ARMY-20-2554, 20-2562-A-000084

[illegible]

MULTI-DOD-ARMY-20-2554, 20-2562-A-000086

[illegible]

MULTI-DOD-ARMY-20-2554, 20-2562-A-000088

MULTI-DOD-ARMY-20-2554, 20-2562-A-000089

[illegible]

MULTI-DOD-ARMY-20-2554, 20-2562-A-000091

MULTI-DOD-ARMY-20-2554, 20-2562-A-000092

[illegible]

[illegible]

[illegible]

[illegible]

MULTI-DOD-ARMY-20-2554, 20-2562-A-000097

[illegible]

MULTI-DOD-ARMY-20-2554, 20-2562-A-000099

MULTI-DOD-ARMY-20-2554, 20-2562-A-000100

MULTI-DOD-ARMY-20-2554, 20-2562-A-000101

MULTI-DOD-ARMY-20-2554, 20-2562-A-000102

[illegible]

(b) (4)

MULTI-DOD-ARMY-20-2554, 20-2562-A-000105

MULTI-DOD-ARMY-20-2554, 20-2562-A-000106

ATTACHMENT 2:

Additional OPSEC Requirements

ATTACHMENT 3:**Material Threats**Biological Threats

- 1 Bacillus anthracis (anthrax) and Multi-drug resistant B. anthracis (MDR anthrax)
- 2 Burkholderia mallei (glanders) and Burkholderia pseudomallei (melioidosis)
- 3 Clostridium botulinum toxin (botulism)
- 4 Ebola virus (Ebola hemorrhagic fever)
- 5 Francisella tularensis (tularemia)
- 6 Marburg virus (Marburg hemorrhagic fever)
- 7 Pandemic influenza
- 8 Rickettsia prowazekii (typhus)
- 9 Variola virus (smallpox)
- 10 Yersinia pestis (plague)

Chemical Threats

- A. Acetylcholinesterase inhibitor nerve agents
- B. Chlorine
- C. Cyanide salts (potassium and sodium cyanide)
- D. Hydrogen cyanide
- E. Phosgene
- F. Vesicants

SECTION B - SUPPLIES OR SERVICES AND PRICES**CLIN 0058**

The CLIN extended description has changed from:

PLACE HOLDER - RPP 20-11 Objective 20-11 is being authorized under CLIN 0058 for "Janssen's COVID-19 Vaccine – Large Scale Domestic Production." The total approved cost by the Government for this effort is not to exceed \$1,010,000,000.00. The total amount authorized to Janssen is \$1,001,650,000.00. The total amount authorized to ATI is \$8,350,000.00 (broken out as \$8,350,000.00 Cost and \$0.00 Fixed Fee).

To:

RPP 20-11 Objective 20-11 is being awarded under CLIN 0058 for "Janssen's COVID-19 Vaccine – Large Scale Domestic Production." The total approved cost by the Government for this effort is not to exceed \$1,010,000,000.00. The total amount awarded to Janssen is

\$1,001,650,000.00. The total amount authorized to ATI is \$8,350,000.00 (broken out as \$8,350,000.00 Cost and \$0.00 Fixed Fee).

SUBCLIN 005802 is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
005802	Funding for CLIN 0058 CPFF Funding is being added to CLIN 0058 in the amount of \$999,999,999.99. The total amount awarded to Janssen is \$999,999,999.99. The total amount awarded to ATI is \$0.00 (broken out as \$0.00 Cost and \$0.00 Fixed Fee). PURCHASE REQUEST NUMBER: 0011532810				\$0.00
				ESTIMATED COST	\$0.00
				FIXED FEE	\$0.00
					\$0.00
				TOTAL EST COST + FEE	
	ACRN GT				\$999,999,999.99
	CIN: GFEBS001153281000001				

SUBCLIN 005803 is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
005803	Funding for CLIN 0058 CPFF Funding is being added to CLIN 0058 in the amount of \$1,650,000.01. The total amount awarded to Janssen is \$1,650,000.01. The total amount awarded to ATI is \$0.00 (broken out as \$0.00 Cost and \$0.00 Fixed Fee). PURCHASE REQUEST NUMBER: 0011532810				\$0.00
				ESTIMATED COST	\$0.00
				FIXED FEE	\$0.00
					\$0.00
				TOTAL EST COST + FEE	
	ACRN GU				\$1,650,000.01
	CIN: GFEBS001153281000002				

SECTION E - INSPECTION AND ACCEPTANCE

The following Acceptance/Inspection Schedule was added for SUBCLIN 005802:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
N/A	N/A	N/A	N/A

The following Acceptance/Inspection Schedule was added for SUBCLIN 005803:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
N/A	N/A	N/A	N/A

SECTION G - CONTRACT ADMINISTRATION DATA

Accounting and Appropriation

Summary for the Payment Office

As a result of this modification, the total funded amount for this document was increased by \$1,001,650,000.00 from \$6,328,970,669.79 to \$7,330,620,669.79.

SUBCLIN 005802:

Funding on SUBCLIN 005802 is initiated as follows:

ACRN: GT

CIN: GFEB001153281000001

Acctng Data: 0212020202120400000664643255 S.0074658.5.14 6100.9000021001

Increase: \$999,999,999.99

Total: \$999,999,999.99

Cost Code: A5XAH

SUBCLIN 005803:

Funding on SUBCLIN 005803 is initiated as follows:

ACRN: GU

CIN: GFEB001153281000002

Acctng Data: 0212020202120400000664643255 S.0074658.5.14.1 6100.9000021001

Increase: \$1,650,000.01

Total: \$1,650,000.01

Cost Code: A5XAH

(End of Summary of Changes)

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT				1. CONTRACT ID CODE		PAGE OF PAGES 1 5	
2. AMENDMENT/MODIFICATION NO. P00005		3. EFFECTIVE DATE 22-Mar-2020		4. REQUISITION/PURCHASE REQ. NO. SEE SCHEDULE		5. PROJECT NO.(If applicable)	
6. ISSUED BY W6QK ACC-APG NATICK CONTRACTING DIVISION BLDG 1 GENERAL GREENE AVENUE NATICK MA 01760-5011		CODE W911QY		7. ADMINISTERED BY (If other than item 6) W6QK ACC-APG NATICK 110 THOMAS JOHNSON DR SUITE #240 FREDERICK MD 21702		CODE W911QY	
8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code) OLOGY BIOSERVICES, INC NANOTHERAPEUTICS 13200 NW NANO COURT ALACHUA FL 32615-8726				9A. AMENDMENT OF SOLICITATION NO.			
				9B. DATED (SEE ITEM 11)			
				X 10A. MOD. OF CONTRACT/ORDER NO. W911QY2090003			
				X 10B. DATED (SEE ITEM 13) 22-Feb-2020			
CODE 3GQS9		FACILITY CODE					
11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS							
☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer ☐ is extended, ☐ is not extended. 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: (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.							
12. ACCOUNTING AND APPROPRIATION DATA (If required) See Schedule							
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) In accordance with Article 5 of the Agreement							
E. IMPORTANT: Contractor ☐ is not, ☒ is required to sign this document and return <u>1</u> 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 amendment is to incorporate Project 20-04 under CLN 0004, incorporate incremental funding, and revise Article 14.G. All other terms and conditions remain the same 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)			
				TEL: (b) (6) EMAIL: (b) (6)			
15B. CONTRACTOR/OFFEROR		15C. DATE SIGNED		16B. UNITED STATES OF AMERICA (b) (6)		16C. DATE SIGNED	
(Signature of person authorized to sign)				BY (b) (6)		22-Mar-2020	
				(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:

P00005

- A. The purpose of this amendment is as follows:
- a. Paragraph A.1 of modification P00002 is hereby changed from:
 - 1. Project 20-05, Rapid Production of Monoclonal Antibodies as Medical Countermeasures against COVID-19, Attachment 1, is hereby incorporated into the agreement under CLIN 0002.
 - To:
 - 1. Project 20-05, Rapid Production of Monoclonal Antibodies as Medical Countermeasures against COVID-19, Appendix A-2, is hereby incorporated into the agreement under CLIN 0002.
 - b. The SOW for Project 20-04, Rapid COVID-19 Plasmid Manufacturing for Phase 1 Clinical Programs, dated 22 Mar 2020, Appendix A-4, is hereby incorporated into the agreement under CLIN 0004.
 - c. The total cost of the agreement is hereby increased by (b) (4) [REDACTED]
 - d. SubCLIN 000401 is hereby added to the agreement into incorporate incremental funding in the amount of (b) (4) [REDACTED] under ACRN AB.
 - e. Article 14.G is hereby replace in its entirety with "Any project order incorporated into this agreement may be DO C-9 rated order certified for national defense, emergency preparedness, and energy program use under the Defense Priorities and Allocations System (DPAS) (15 CFR700), and the Awardee will be required to follow all of the requirements of this regulation.
 - f. Projects 20-01, 20-02, 20-03, and 20-04 are hereby rated DO C-9 in accordance with Article 14.G.
- B. The parties hereby agree that changes effected by this amendment constitute both the consideration and the equitable adjustment due under any Article in this agreement resulting from the incorporation of Project 20-04.
- C. All other terms and conditions remain the same and in full force and effect.

The following have been modified:
P00004

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000301	GFY 2020 Funding CPFF Project 20-03 PURCHASE REQUEST NUMBER: 0011473355				\$0.00
				ESTIMATED COST	\$0.00
				FIXED FEE	\$0.00
				TOTAL EST COST + FEE	\$0.00
	ACRN AC CIN: GFEBS001147335500001				(b) (4)

SECTION A - SOLICITATION/CONTRACT FORM

The total cost of this contract was increased by (b) (4)

SECTION B - SUPPLIES OR SERVICES AND PRICES

CLIN 0004 is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0004			Job		(b) (4)

PROJECT 20-04: COVID DNA

CPFF

Project 20-04: Rapid COVID-19 Plasmid Manufacturing for Phase 1 Clinical Programs labor, materials, equipment and associated allowable costs delineated the in Statment of Work entitled, "Procurement, Commissioning and Qualification of Two 300 L Single-Use Fermentors at the DoD ADM Facility," hereby incorporated into the Agreement as Appendix A-4.

The project level Agreements Officer Representative shall be the Government's representative on technical matters related solely to this project.

The project level AOR does not supersede the roles and duties of the Agreement AOR. The Project AOR's contact Information is below:

Name: (b) (6)

FOB: Destination

PSC CD: AN14

ESTIMATED COST	(b) (4)
FIXED FEE	(b) (4)
TOTAL EST COST + FEE	(b) (4)

SUBCLIN 000401 is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
000401					\$0.00

FY 20 Funding

CPFF

PURCHASE REQUEST NUMBER: 0011474201

ESTIMATED COST	\$0.00
FIXED FEE	\$0.00
TOTAL EST COST + FEE	\$0.00

ACRN AB

CIN: GFEB001147420100001

(b) (4)

SECTION E - INSPECTION AND ACCEPTANCE

The following Acceptance/Inspection Schedule was added for CLIN 0004:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
Destination	Government	Destination	Government

The following Acceptance/Inspection Schedule was added for SUBCLIN 000401:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
N/A	N/A	N/A	N/A

SECTION F - DELIVERIES OR PERFORMANCE

The following Delivery Schedule for CLIN 0004 has been added:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
31-MAR-2022		N/A FOB: Destination	

SECTION G - CONTRACT ADMINISTRATION DATA

Accounting and Appropriation

Summary for the Payment Office

As a result of this modification, the total funded amount for this document was increased by (b) (4)

SUBCLIN 000401:

Funding on SUBCLIN 000401 is initiated as follows:

ACRN: AB

CIN: GFEB001147420100001

Acctng Data: 09720202021013000018170446463252 S.0025760.7.5.1 6100.9000021001

Increase: (b) (4)

Total: (b) (4)

Cost Code: AHPII

(End of Summary of Changes)

10 USC 2373 AGREEMENT

BETWEEN

Ology Bioservices, Inc. (Awardee or Contractor)

13200 NW Nano Court

Alachua, FL 32615

And

NATICK CONTRACTING DIVISION (Government)

110 Thomas Johnson Dr.

Frederick, MD 21702

Effective Date: 21 Feb 2020

Agreement No.: W911QY-20-9-0003

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

Ology Bioservices, Inc.

(b) (6) Date: 2020.02.21 19:07:36 -05 00

Signature

(b) (6)

Printed Name

Senior VP, Government Contracts

Title

21 February 2020

Date

Government

(b) (6)

(b) (6)

1033291600
2020.02.21 19:16:05 -05 00

Signature

(b) (6)

Printed Name

Agreements Officer

Title

21 Feb 2020

Date

ARTICLE 1. Scope.

A. This 10 U.S.C. § 2373 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. § 2373 and is not a procurement contract governed by the Federal Acquisition Regulation (FAR), a grant, cooperative agreement, or 10 U.S.C. § 2371(b) other transaction agreement. The FAR and the Defense Federal Acquisition Regulation Supplement (DFARS) apply only as specifically referenced herein. This Agreement is not intended to be, nor will it be construed as, forming, by implication or otherwise, a partnership, a corporation, or other business organization. This Agreement is not subject to the Bayh-Dole Act, 35 U.S.C. §§ 200-212.

B. The 2018 National Defense Authorization Act (NDAA) amended 10 U.S.C. § 2358 to add 10 U.S.C. § 2373 as “authorized means” of Defense contracting for research and development projects (Pub. L. 115–91, div. A, title VIII, § 862, Dec. 12, 2017, 131 Stat. 1495) and expressed a preference for use of 10 U.S.C. § 2373 for certain contracting actions: “In the execution of science and technology and prototyping programs” (Pub. L. 115–91, div. A, title VIII, § 867, Dec. 12, 2017, codified at 10 U.S.C. § 2371 note).

C. This Agreement meets all criteria necessary for 10 U.S.C. § 2373 contracting actions. Consistent with the stated purpose of the statute, the Parties agree that scope and the ultimate purpose of this Agreement is to acquire chemical activity and medical supplies and designs thereof necessary for experimental or test purposes in the development of the best supplies needed for national defense. Examples of supplies for purposes of this Agreement include manufacturing platforms, compounds, drug product, drug substance, conformance lots, optimized products, shakedown/engineering/ development runs, equipment, and materials. All supplies purchased for testing and experimental purposes under this Agreement are necessary to develop the best supplies for national defense, such as Food and Drug Administration (FDA) licensed vaccines and therapeutics.

D. This Agreement will facilitate multiple projects for development of specific supplies required by the Government within the scope of the Agreement as described herein, each of which will be described in a Statement of Work (SOW).

E. Each project facilitated by this Agreement, will produce quantities of supplies that are necessary for experimentation and technical evaluation of those supplies only. Any project with multiple SOWs shall not, in the aggregate, exceed the quantity necessary for experimentation and technical evaluation. All SOWs executed under this Agreement shall be within the scope of the Agreement as described herein. The Parties agree that this Agreement is not intended to, and does not authorize purchase of chemical activity and medical supplies and designs thereof in quantities greater than those necessary for experimental or test purposes in the development of the best supplies needed for national defense. Accordingly, the requirements of 10 USC Chapter 137 are not applicable to this Agreement or any SOW issued hereunder.

F. (b) (4)

The ADMF was built to the specification of the Department of Defense to be biosafety level 3, who continue to own the Government Equipment within the ADMF that is critical for the safety of the employees, functionality of the building and success of the government projects.

G. In consideration of the guaranteed minimum amount established under this Agreement, the Awardee will provide research and development to complete the deliverables described in each order's Statements of Work up to the stated maximum. The minimum amount of this Agreement shall be \$1,000,000.00 for the Term and the maximum amount of this Agreement shall be \$90,000,000.00 for the Term.

ARTICLE 2. Term and Termination.

A. Term: The Term of this Agreement commences upon the Effective Date and extends for a period of six (6) years (the Term). SOWs may be incorporated at any time during the Term and the delivery date of any such SOW may extend beyond the end of the Term.

B. Termination for Convenience: The Government may terminate this Agreement for any or no reason by providing at least one hundred eighty (180) 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. Termination of this Agreement will not impact ongoing projects which were awarded prior to the notice of termination under this Agreement.

C. Termination for Cause: If the Awardee materially fails to comply with the provisions of this Agreement, the Agreement Officer (AO), after issuance of a cure notice and failure of the Awardee to cure the defect within thirty (30) calendar days or the time allowed by the AO 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, including the termination of one or more SOWs issued under this Agreement,
- (iv) withhold further funding,
- (v) require Awardee to pay repurchase costs as defined in Article 2C1, Repurchase Against Contractors Account, or
- (vi) take any other legally available remedies.

1. Repurchase Against Contractors Account.

- a. When the supplies are still required after termination, the AO shall repurchase the same or similar supplies against the Contractor's account as soon as practicable. The AO shall repurchase at as reasonable a price as practicable, considering the quality

and delivery requirements. The AO may repurchase a quantity in excess of the undelivered quantity terminated for cause when the excess quantity is needed, but excess cost may not be charged against the Contractor for more than the undelivered quantity terminated for cause (including variations in quantity). The AO will make a decision whether or not to repurchase before issuing the termination notice.

- b. If repurchase is made at a price over the price of the supplies terminated, the AO shall, after completion and final payment of the repurchase contract or agreement, make written demand on the Contractor for the total amount of the excess, giving consideration to any increases or decreases in other costs such as transportation, discounts, etc. If the Contractor fails to make payment, the AO shall follow the procedures in FAR subpart 32.6 for collecting contract debts due the Government.

2. Termination for Cause Procedures.

If this Agreement is terminated for Cause in whole or in part, Awardee will grant the Government a non-exclusive, paid up, perpetual license to the patents and documentation necessary for the purpose of continuing development of all deliverables that were subject to the termination. Additionally, the Awardee shall provide the U.S. Government or its designee with a non-exclusive, paid up, license to any patent, copyright, technical data or regulatory information directly related to those terminated deliverables to permit the U.S. Government to pursue commercialization of the technology with a third party, on terms to be agreed between the Parties and subject to rights granted or held by third parties. The terms of this section and the obligations herein will be included in any exclusive license given by the Awardee to a third party for any intellectual property covered by this Agreement, on terms to be agreed between Awardee and such third party. This clause will survive the acquisition or merger of the Awardee by or with a third party.

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: Except as noted in Article 2.C., 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 concerning SOW's directly associated with this Agreement. 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 Contactor's organization shall be established with authority to effectively complete the deliverables. This organization shall become effective upon execution of this Agreement and its integrity shall be maintained until the deliverable(s) is/are accepted by the Government. The key personnel listed in the applicable SOW are considered to be critical to the successful performance of this Agreement. Prior to replacing these key personnel, the Awardee shall provide written notification to the AO. The Awardee shall demonstrate that the qualifications of the proposed substitute personnel are generally equivalent to or better than the qualifications of the personnel being replaced.

D. Subcontract Approval: Modifications to subcontracts 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 AO prior to being executed.

ARTICLE 4. Agreement Administration.

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

Government Representatives:

Agreements Officer (AO)

(b) (6)

Agreement Specialists (AS)

Primary	Alternate
(b) (6)	

Awardee Representatives:

(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 pursuant to separately issued orders issued for specific requirements within the Scope of the Agreement (the "Orders"). Orders shall be issued as modifications to this Agreement. Each Order shall incorporate additional SOWs. In consideration of Government funding under this Agreement, the Awardee will provide research and development to complete the deliverables described in each SOW, which are incorporated herein and attached hereto as Appendix A. The first SOW shall be Appendix A-1, the next Appendix A-2, the next Appendix A-3, etc.

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 AO. This letter will detail the technical, chronological and financial impact, if any, of the proposed modification to the project. Any resultant modification is subject to the mutual agreement of the Parties. The Government is not obligated to pay for additional or revised costs unless and until this

Agreement is formally revised by the AO and made part of this Agreement. Any modification to this Agreement to account for recommended changes in the SOW or Payable Milestones will be considered a supplemental agreement.

C. Review of Recommendations: The AO will be responsible for the review and verification of any recommendations to revise or otherwise modify the Agreement, the SOW, or other proposed changes to the terms and conditions of this Agreement.

D. Government Changes. The Government may issue unilateral, within scope changes to the work called for under this Agreement, which the Awardee shall perform pending finalization of the Agreement's modification reflecting the change and associated costs. The Awardee will be reimbursed for costs incurred that are reasonable, allowable and allocable to the work performed as required by the Government's mandated change. In addition, the Government may unilaterally make minor or administrative no-cost agreement modifications (e.g., changes in the paying office or appropriation data, changes to Contractor personnel proposed by Contractor, 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 the AO.

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 C.

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 AO. The AO will review the matter and render a decision in writing. Any such decision is final and binding. In the event of a decision, within (60) calendar days of the referral for review (or such other period as agreed upon by the parties), either party may pursue any right or remedy provided by law in a court of competent jurisdiction as authorized by 28 U.S.C. 1491. Alternately, the parties may agree to explore and establish and Alternate Disputes Resolution procedure to resolve this dispute.

I. Quality Agreement. A Quality Agreement will be developed separately for each Order exercised under this Agreement.

ARTICLE 6. INSPECTION/ACCEPTANCE

A. Inspection: The Government has the right to inspect and test all work called for by the applicable SOW during the period of performance. The Government or its designee, including

employees and contractors of the FDA, may inspect the areas of premises of the Awardee or any subawardee that are specifically designated to the performance of the work under the applicable SOW. Inspections and testing will be requested and scheduled between the Government Project Manager (or its designee) and Awardee Project Manager. The Government shall perform inspections and tests in a manner that will not unduly delay the work, and during an agreeable time and date for both the Government and Awardee (subawardee). If the Government performs any required 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 after completion/delivery, unless otherwise specified in the Agreement. 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 deliverable(s) performed at Awardee's facility shall not exceed 120 days after completion. The Government waives the right to reject nonconforming work should it fail to notify the Awardee within the 120 days of delivery, unless otherwise specified in the applicable SOW. Acceptance of the work shall be conclusive. The Government shall notify the Awardee, and separately negotiate storage of a deliverable, if storage of the work is anticipated to exceed 120 days.

ARTICLE 7. Financial Matters

This is an expenditure-based 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 project based on the estimated cost.

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 as set forth in Appendix B. The schedule is predicated upon the Government's fiscal year, which begins on October 1 of each calendar 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 Government may incrementally fund this agreement. The amount of Government funds obligated by this Agreement and available for payment is set forth in the Line of Accounting and Appropriation, or subsequent amendments providing incremental funding.

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 prices 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 processed in WAWF and should be made within thirty (30) calendar days of receipt of a request for payment.

E. WIDE AREA WORKFLOW PAYMENT INSTRUCTIONS

(a) Definitions.

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

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

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

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

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

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

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

(f) WAWF payment instructions. The Awardee must use the following information when submitting payment requests and receiving reports in WAWF for this contract/order:

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

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

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

Routing Data Table*

<i>Field Name in WAWF</i>	<i>Data to be entered in WAWF</i>
Pay Official DoDAAC	(b) (4)
Issue By DoDAAC	(b) (4)
Admin DoDAAC	
Inspect By DoDAAC	(b) (4)
Ship To Code	(b) (4)

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

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

(b) (6)

(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.

F. Comptroller General Access to Records. To the extent that the total Government payments under this Agreement exceed \$5,000,000, the Comptroller General, at its discretion, shall have access to and the right to examine records of any Party to the Agreement or any entity that participates in the performance of this Agreement that directly pertain to, and involve transactions relating to, the Agreement for a period of three (3) years after final payment is made. This requirement shall not apply with respect to any Party to this Agreement or any entity that participates in the performance of the Agreement, or any subordinate element of such Party or entity, that has not entered into any other agreement (contract, grant, cooperative agreement, or "other transaction") that

provides for audit access by a government entity in the year prior to the date of this Agreement. This paragraph only applies to any record that is created or maintained in the ordinary course of business or pursuant to a provision of law. The terms of this paragraph shall be included in all sub-agreements to the Agreement other than sub-agreements with a component of the U.S. Government. The Comptroller General may not examine records pursuant to a clause included in an agreement more than three years after the final payment is made by the United States under the agreement.

ARTICLE 8. Reserved

ARTICLE 9. Intellectual Property Rights

The Parties agree that the terms in this Article apply generally to this Agreement, and that the terms may be modified in any SOW issued under this Agreement by mutual agreement of the Parties. If a SOW does not address intellectual property rights, the terms of this Article will govern intellectual property rights related to that SOW. To the extent there is any conflict between this Article and the intellectual property rights provision contained in a SOW, the terms of the SOW shall control.

A. Background Intellectual Property 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 this Agreement will enter into an agreement with any manufacturer or other third party whereby the third party will obtain rights in Agreement Inventions or Study Data, as those terms are defined in this Agreement, absent the mutual consent of the parties to the awarded contract.

B. Definitions. For purposes of this agreement, an “Agreement Invention” is 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.

C. Awardee’s Background IP. Prior to the issuance of any SOW, Awardee shall disclose Background IP which contain claims that are related to research contemplated under the SOW, and shall provide identifying information to the Government. No license(s) to any patent applications, issued patents, or Background IP shall be granted under this Agreement, and are specifically excluded from the definitions of “Agreement Invention” contained in this Agreement.

D. 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 notified of such claims and proceedings as soon as practicable by the Government of the suit or action alleging such infringement and shall have been given such opportunity as is

afforded by applicable laws, rules, or regulations to participate in its defense. Further, this indemnity shall not apply to-

An infringement resulting from compliance with specific written instructions of the AO directing a change in the supplies to be delivered or in the materials or equipment to be used, or directing a manner of performance of the contract not normally used by the Contractor; An infringement resulting from addition to or change in supplies or components furnished subsequent to delivery or performance; or a claimed infringement that is unreasonably settled without the consent of the Contractor, unless required by final decree of a court of competent jurisdiction.

E. Patent Prosecution. Awardee agrees to take responsibility for the preparation, filing, prosecution, and maintenance of any and all patents and patent applications listed as Awardee Background IP that are relevant to work performed under this Agreement. 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 Agreement 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 10 shall restrict the Government in its preparation, filing, prosecution and maintenance of a patent or patent application covering an Agreement Invention.

F. Patent Enforcement. Awardee will have the first option to enforce any patent rights covering an Agreement 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 Agreement Invention only with Awardee's prior written approval.

G. Ownership. 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 (Agreement 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 Agreement Inventions will accrue to the inventor or inventor-organization. The Parties represent and warrant that each inventor will assign his or her rights in any such inventions to his or her employing organization. If either an Awardee employee or a Government employee makes a sole Agreement Invention, the entire rights to that Agreement Invention will be respectively assigned to the Awardee or the Government. If an Awardee employee and a Government employee jointly make an Agreement Invention, it will be owned jointly by the Awardee and the Government. Ownership of Agreement Inventions made in whole or in part with subawardee employees, including employees of other components of the Government, will be determined solely pursuant to an agreement between the Awardee and the applicable subawardee.

H. Patent Applications. The Parties will respectively have the option to file a patent application claiming any Agreement 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 Agreement Invention. Within thirty (30) calendar days of being notified of the discovery of an Agreement Invention or filing a patent application

covering an Agreement 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 Agreement Invention. Any Party filing a patent application will bear expenses associated with filing and prosecuting the application, as well as maintaining any patents that issue from the application, unless otherwise agreed by the Parties.

I. Licenses. For each Agreement Invention made solely by the Awardee, the Government will receive a non-exclusive, worldwide, transferable, paid-up, royalty-free, irrevocable license to practice the invention and the right to sublicense same to third parties to practice the invention for any Government purpose, including but not limited to continuing research and development related to the Agreement Invention, and eventual regulatory approval and commercialization thereof. The Government will receive a right of first refusal for an exclusive license to the Agreement Invention, subject to no less than a (b) (4) royalty rate based on gross royalty revenue received by the Government. For any Agreement Invention made solely by the Government, the Awardee will receive a non-exclusive, worldwide, transferable, paid-up, royalty-free, irrevocable license to practice the Agreement Invention or allow a third party to practice the invention for any purpose. The Awardee will receive a right of first refusal for an exclusive license to the Agreement Invention for purposes of FDA licensure of the technology described herein for the indication described herein, subject to a termination terms substantially similar to the events described in Section 11(e) below.

J. Awardee shall report any Agreement Inventions to the Government within 60 days of the time it was conceived or first reduced to practice under this Agreement. Executive Order No. 9424 of 18 February 1944 requires all executive Departments and agencies of the Government to forward through appropriate channels to the Commissioner of Patents and Trademarks, for recording, all Government interests in patents or applications for patents.

ARTICLE 10. Data Rights.

The Parties agree that the terms in this Article 10 apply generally to this Agreement, and that the terms may be modified in any SOW issued under this Agreement by mutual agreement of the Parties. If a SOW does not address data rights, the terms of this Article 10 will govern data rights related to that SOW. To the extent there is any conflict between this Article 11 and the data rights provision contained in a SOW, the terms of the SOW shall control.

A. For purposes of this Agreement, "Study Data" is all data generated in connection with the performance of the studies under this Agreement. Study Data shall be owned by the Awardee. The U.S. Government shall have the right to use, modify, reproduce, release, perform, display, or disclose data first produced in the performance of this Agreement within the Government and otherwise 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

material or data to the extent that such material or data was produced outside the scope of this Agreement.

Notwithstanding the above, as a result of this Agreement, the Government shall obtain "Unlimited rights," as this term is defined in DFARS 252.227-7013(a)(16) specific to any Study Data generated under, and as a result of this Agreement.

B. The Awardee agrees to retain and maintain in good condition until five (5) years after completion or termination of this Agreement, all Study 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 Study Data, in Awardee's possession and developed under this Agreement, necessary to deliver the supplies identified on the particular SOW within sixty (60) calendar days from the date of the written request.

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

"Use, duplication, or disclosure is subject to the restrictions as stated in Agreement No. W911QY-20-9-XXXX between the Government and the Awardee."

Any rights that the Awardee or the Government may have in Study 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.

D. All Technical Data and Software (each term as defined under DFARS 252.227-7013) which shall be delivered under this Agreement with less than unlimited rights shall be identified with reasonable specificity and particular rights granted (Government Purpose, Limited or Restricted (all as defined in DFARS 252.227-7013)) in a data rights assertions list supplied to the Government, for review and evaluation, prior to entering into the agreement for the applicable SOW. 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 11. Regulatory Rights.

The Parties agree that the terms in this Article 11 apply generally to this Agreement, and that the terms may be modified in any SOW issued under this Agreement by mutual agreement of the Parties. If a SOW does not address regulatory rights, the terms of this Article 11 will govern regulatory rights related to that SOW. To the extent there is any conflict between this Article 11 and the data rights provision contained in a SOW, the terms of the SOW shall control.

This Agreement may include research with one or more investigational drug, biologic or medical device that is regulated by the U.S. Food and Drug Administration (FDA) and requires FDA pre-market approval or clearance before commercial marketing may begin. Subject to further negotiation between the parties and set forth in the SOW, the Contractor may 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 controls research under this agreement. The Sponsor of the Regulatory Application to FDA (as the terms “sponsor” and “applicant” are defined or used in at 21 CFR §§3.2(c), 312.5, 600.3(t), 812.2(b), 812 Subpart C, or 814.20) has certain standing before the FDA that entitles it to exclusive communications related to the Regulatory Application.

With respect to any products regulated by the FDA, the Contractor agrees to the following:

- a. The Contractor shall 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 under this Agreement. In addition, the Contractor will offer the Government the opportunity to review and provide comments on a final draft of regulatory submissions which include data funded under this Agreement. The Government will review any such submissions promptly upon receipt. The Contractor shall reasonably consider any comments provided by the Government, and prior to submission shall provide notification to the Government of any additional edits or revisions. The Contractor shall keep the Government reasonably apprised of planned FDA meetings and post-meeting outcomes relating to activities funded under this Agreement.
- b. Communications. The Contractor shall provide the Government with all communications and summaries thereof, both formal and informal, to or from FDA regarding the regulatory submissions subject to this Agreement and ensure that the Government representatives are invited to participate in any formal Sponsor meetings with the FDA. The Contractor shall use its best efforts to ensure that the Government representatives are invited to participate in any informal Sponsor meetings with the FDA so long as the Contractor has 48 hour advance notice of such Sponsor meeting from the FDA prior to the scheduled meeting time.
- c. Non-compliance with section (b) may result in termination of the agreement.
- d. Product Development Failure. Certain product development failures may trigger certain remedies in Section “e.” below for the Government advanced developer funding the development of the work contemplated in the applicable SOW. This remedy is not available to the Government for any cause outside of the following:
 - (i) if this agreement is terminated for nonperformance; or
 - (ii) the Contractor gives notice, required to be submitted to the Government no later than 30 business days, of any formal management decision to terminate this product development effort pre-market or to file for Federal bankruptcy protection.
- e. If any of the product development failures listed in section “d” occur, the Contractor, 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 (e)(i) above; and
 - (iii) shall negotiate in good faith a non-exclusive license, at customary industry rates and under reasonable terms and conditions, to any patent, copyright or other intellectual property owned or controlled by the Contractor, developed prior to or outside the scope of this agreement, or any technical data that is necessary for the Government to pursue commercialization of this technology with a third party for sale to the Government or otherwise.
- f. This clause will survive the acquisition or merger of the Contractor by or with a third party. This clause will also be included in any subcontracts/sub agreements relating to the development of the Technology. This clause will survive the expiration of this agreement.

ARTICLE 12. Foreign Access to Data.

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

ARTICLE 13. Scientific Publications and Press Releases.

A. The Parties shall jointly agree on a publication plan for the data derived from studies executed under this Agreement (such data to be considered New Data). 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 Monthly Progress Reports, the Awardee will share the publication plan with the Government.

B. 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.

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

D. The Parties will jointly agree on whether to issue one or more press releases related to the resulting New 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.

ARTICLE 14. 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 Articles 10 and 11, 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 Agreements Officer has given prior written approval or (ii) the information is otherwise in the public domain before the date of release.

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. Priority Access.

1) Defense Priority and Allocations Requirements. This Agreement, and each Order placed under this Agreement may be a rated order certified for national defense and emergency

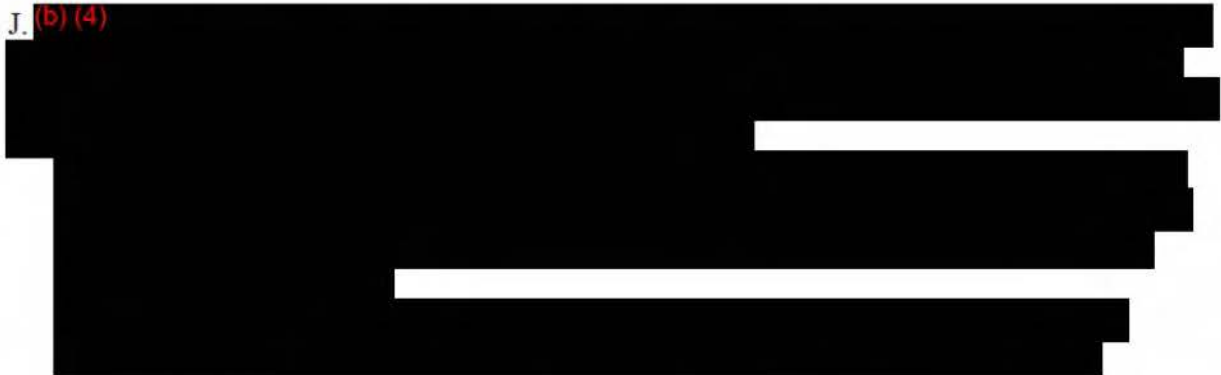
preparedness, and the Contractor shall follow all requirements of the Defense Priorities and Allocations System (DPAS) regulation (15 CFR 700).

2) Reserved.

H. Assignment. Awardee shall not engage in any sale, transfer, merger or acquisition that would require novation in accordance with FAR 42.1204(a) without the prior written consent of the AO, which shall not be unreasonably withheld. Once the transfer is complete, novation shall be governed by FAR 42.1204, which is hereby incorporated by reference. Awardee may engage in a sale, transfer, merger or acquisition that does not require a novation in accordance with FAR 42.1204(b) without the written consent of the Government, provided that the Awardee provides a written agreement evidencing the assignee's intent to continue work within the Agreement Scope and obligate itself to the terms and conditions of this Agreement.

I. Foreign Investment. In addition to the requirements above in subsection (H), prior to the close of any "covered transaction," as that term is defined by 50 U.S.C. 4565(a)(4), Contractor shall make a voluntary submission of information related to the covered transaction to the Committee on Foreign Investment in the United States ("CFIUS"). The CFIUS package shall be submitted to the AO for review and comment 10 business days in advance of Contractor's voluntary submission to CFIUS. For the purposes of determining whether a transaction is a "covered transaction," the parties acknowledge that the ADM Facility is "critical infrastructure" that, during the term of this Agreement, may be used to produce "critical technologies" in support of "national security," as those terms are defined in 50 U.S.C. 4565(a). Contractor agrees to follow any recommendations issued throughout the CFIUS process, including any determinations with respect to permissibility of the transaction.

J. (b) (4)



K. 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.

L. 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) each SOW as included in Appendix A, (ii) the Articles of this Agreement, and (iii) other Appendices to the Agreement.

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NATICK CONTRACTING DIVISION

BY: (b) (6) Date: 2020.02.21 19:07:07 -05 00

BY: [REDACTED]

NAME: (b) (6)

NAME: (b) (6)

TITLE: Senior VP, Government Contracts

TITLE: Agreements Officer

DATE: 21 February 2020

DATE: 21 Feb 2020

(b) (4)

|

Appendix B

Project Schedule Payment Schedule

The Government shall pay the Contractor, upon the submission of proper invoices or vouchers. 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 work. The Awardee must maintain a financial system capable of identifying costs applicable to this Agreement, compliant with Cost Principles (48 CFR Part 31). 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 indirect 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 AO and be in writing, of which email is an acceptable form.

Appendix C Government Property

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

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

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

Use	Description	Make/Model	Est. Cost
Project Specific Equipment Requirements			

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 AO, 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 AO.

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

Awardee Liability for Government Property. “Loss of Government Property” means the loss, damage or destruction to Government Property reducing the Government’s expected economic benefits of the property and includes loss of accountability but does not include planned and purposeful destructive testing, obsolescence, normal wear and tear or manufacturing defects. THE AWARDEE SHALL BE LIABLE FOR LOSS OF GOVERNMENT PROPERTY IN AWARDEE’S POSSESSION, EXCEPT WHEN ANY ONE OF THE FOLLOWING APPLIES: (I) AO 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; OR (III) GOVERNMENT PROPERTY IS DISPOSED OF IN ACCORDANCE WITH THE GOVERNMENT’S DIRECTIONS.



**DEPARTMENT OF THE ARMY
U.S. ARMY CONTRACTING COMMAND – NEW JERSEY
PICATINNY ARSENAL, NEW JERSEY 07806-5000**

REPLY TO
ATTENTION OF

21 July 2020

Army Contracting Command – New Jersey
ACC-NJ, Building 9
Picatinny Arsenal, NJ 07806

SUBJECT: Technical Direction Letter for Medical CRBN Defense Consortium (MCDC), Request for Prototype Proposals (RPP) 20-11, Objective PRE-20-11 for “COVID-19 Pandemic – Large Scale Vaccine Manufacturing Demonstration” (Pfizer, Inc.)

REF: Prizer Request for Technical Direction Letter, RPP 20-11 under OTA W15QKN-16-9-1002 for Objective PRE-20-11, dated 20 July 2020

Advanced Technology International
ATTN: (b) (6), Sr. Contracts Manager
315 Sigma Drive
Summerville, SC 29486

Dear (b) (6),

The Army Contracting Command – New Jersey (ACC-NJ), in supporting the Joint Project Manager – Medical Countermeasure Systems (JPM-MCS), issued MCDC RPP 20-11 on 09 June 2020. Members of the MCDC submitted proposals in accordance with this RPP. The Government received and evaluated all proposal(s) submitted and a Basis of Selection has been executed, selecting Pfizer, Inc. as the awardee. The Government requests that a Firm-Fixed-Price Project Agreement be issued to Pfizer, Inc. to award this proposal under Other Transaction Agreement W15QKN-16-9-1002, to be performed in accordance with the attached Government Statement of Work (SOW).

Based upon the acceptable update of Pfizer, Inc.’s proposal for “COVID-19 Pandemic – Large Scale Vaccine Manufacturing Demonstration” and 1) The Project Agreement Recipient’s concurrence with the requirements included in the Government SOW; 2) An acceptable milestone schedule that meets SOW requirements, and; 3) The price proposed that has been analyzed by the Government, you are hereby directed to issue a Project Agreement to Pfizer, Inc. for the subject project. The total project value has been determined fair and reasonable and Pfizer, Inc.’s proposal has been selected IAW the above referenced Basis of Selection.

The total approved cost to the Government for this effort is not to exceed \$1,950,097,500.00. The break-out of the costs is as follows: \$1,950,000,000.00 to perform project efforts included in the SOW and \$97,500.00 for the Consortium Management Firm (CMF) Administrative Cost. The CMF Administrative Cost was approved as a “Special Allocation” for Operation Warp Speed (OWS) Prototype Projects executed under the MCDC OTA. The effort currently has \$1,950,097,500.00 of available funding, comprised of \$1,950,000,000.00 for the Project Agreement, \$67,500.00 for the CMF Special Allocation, and \$30,000 for other, non G&A, ATI costs, which will be incurred, tracked,

and invoiced in accordance with Article V of the OTA. The COVID-19 work shall be tracked separately using the funding obligated via modification P00076. In alignment with the special allocation conditions, it is noted that this project has a base period of performance (b) (4), with a projected completion date of (b) (4). A customized clause for the special allocation, will be incorporated into the funding modification for this prototype project.

The prime contractor is considered a small business, nontraditional defense contractor, or nonprofit research institution and determined to be providing a significant contribution. The affirmation of business status certifications submitted as part of the proposal are hereby incorporated into the agreement. The contractor shall notify the MCDC CMF of any deviation from the final proposed affirmation of business status certifications that would affect the contributions of the small business, nontraditional defense contractor, or nonprofit research institution as proposed.

In accordance with 10.U.S.C. 2371b(f), and upon a determination that the prototype project for this transaction has been successfully completed, this competitively awarded prototype OTA may result in the award of a follow-on production contract or transaction without the use of competitive procedures.

Points of Contact:

Agreements Specialist:

(b) (6)

E-mail: (b) (6)

Phone: (b) (6)

Agreements Officer:

(b) (6)

E-mail: (b) (6)

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Regards,

X (b) (6)

(b) (6)

Agreements Officer

Signed by: (b) (6)

Attachments:

Attachment 1: MCDC2011-003 – Pfizer - 7-21-2020

Attachment 2: SOW Appendix 1 Clause for MCDC Consortium Other Transaction Authority Agreements

**Statement of Work
For
COVID-19 PANDEMIC--LARGE SCALE VACCINE MANUFACTURING
DEMONSTRATION**

RPP #: 20-11

Project Identifier: 2011-003

Consortium Member: Member

Title of Proposal: COVID-19 Pandemic--Large Scale Vaccine Manufacturing Demonstration

Requiring Activity: Joint mission between the Department of Health and Human Services and Department of Defense to combat COVID-19

1.0 INTRODUCTION, SCOPE, AND OBJECTIVES

1.1 Introduction

This Statement of Work (the "Statement of Work") is hereby entered into, effective as of July 21, 2020, pursuant to that certain Project Agreement by and between MCDC and Pfizer dated as of July 21, 2020 ("this Agreement" or "Project Agreement").

An outbreak of respiratory disease caused by a novel coronavirus was first detected in China in late 2019 and has now spread worldwide, including the United States ("US"). The virus has been named Severe Acute Respiratory Disease Coronavirus-2 ("SARS-CoV-2") and causes Coronavirus Disease 2019 ("COVID-19"). On January 30, 2020, the International Health Regulations Emergency Committee of the World Health Organization ("WHO"), declared the outbreak a "Public Health Emergency of International Concern". On January 31, the US Department of Health and Human Services Secretary ("HHS"), Alex M. Azar II, declared a Public Health Emergency for the US to aid the nation's healthcare community in responding to COVID-19. On March 11, 2020, WHO publicly characterized COVID-19 as a pandemic. On March 13, 2020 the President of the United States declared the COVID-19 outbreak a national emergency. The Government has identified COVID-19 vaccine candidates that are progressing rapidly through advanced research and development activities.

Therefore, in response to a request by the Government, Pfizer is proposing to manufacture at-scale and fill-finish, for provision to the Government, a state-of-the-art candidate vaccine, developed in collaboration with BioNTech and capable of providing protection against the SARS-CoV-2 threat and related coronaviruses, subject to technical, clinical and regulatory success.

Pfizer and BioNTech's program aims to revolutionize the vaccine field by providing an mRNA candidate that, itself, has several key advantages, including the efficiency and flexibility of the platform – which is apparent by the pace of the vaccine development and the unprecedented phase

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1/2/3 trial design that it supports. A clear fundamental difference of this candidate over more traditional modalities, such as viral vector vaccines, is that mRNA is delivered by protein-free lipid nanoparticles, which is believed to abolish the risk of anti-vector immunity and permit boosting to maximize the level and duration of immune responses.

The mRNA vaccine technology is also intended to enable quick scale up of production, which is critical for bringing a COVID-19 vaccine to market to address this urgent medical need while preserving high quality and safety standards.

The intent of this prototype project is to demonstrate that Pfizer has the business and logistics capability to manufacture 100M doses of its currently unapproved mRNA-based COVID-19 vaccine for the Government (b) (4), using the Pfizer/BioNTech unique mRNA delivery system and its associated cold chain requirements, under pandemic conditions. This prototype project aims to significantly accelerate and secure US access to this promising medical countermeasure based on domestic manufacturing.

1.1.1 BACKGROUND

(b) (4), Pfizer and BioNTech entered into an agreement for the co-development and distribution (excluding China) of a potential mRNA-based coronavirus vaccine aimed at preventing COVID-19 infection (the "Pfizer/BioNTech Agreement"). Under the Pfizer/BioNTech Agreement, (b) (4)

for the prevention of COVID-19 (b) (4)

for the prevention of COVID-19 (b) (4)

(b) (4)

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The collaboration has rapidly advanced multiple COVID-19 vaccine candidates into human clinical testing based on BioNTech's proprietary mRNA vaccine platforms, with the objective of ensuring rapid worldwide access to the vaccine, if approved. The collaboration leverages Pfizer's broad expertise in vaccine research and development, regulatory capabilities, and global manufacturing and distribution network. The two companies are jointly conducting clinical trials, and will also work jointly to commercialize the vaccine upon regulatory approval.

Pfizer and BioNTech have already made substantial progress, outside this Statement of Work and without use of any Government funding, towards the demonstration of technical and manufacturing feasibility, including through the initiation of Phase 1/2 studies evaluating the likelihood of safety, tolerability and immunogenicity in the US and in Germany. The goal of the program is to rapidly develop and obtain regulatory licensure for a vaccine for use in adults ≥ 18 years of age, followed by a possible pediatric and/ or maternal indication (to protect ~4M US pregnant women at risk each year). Both companies aspire to have an FDA-approved or authorized vaccine ready for administration in the US by October 31, 2020. Based on current information, Pfizer and BioNTech anticipate a 2-dose per patient regimen.

This Statement of Work is designed toward establishing production capacity and distribution infrastructure sufficient to ensure that doses of the vaccine manufactured under this Agreement can be made available immediately for administration in the US, if clinical trials are successful and the FDA grants an Emergency Use Authorization ("EUA") under Section 564 of the Federal Food, Drug, and Cosmetic Act or Biologics License Application ("BLA") licensure under Section 351(a) of the Public Health Service Act (hereafter "FDA-approved or authorized").

1.1.2 ACTIVITIES UNDERTAKEN WITHOUT GOVERNMENT FUNDING

This section describes activities that Pfizer and BioNTech have been performing and will continue to perform without use of Government funding. These activities are described solely for background and context for the Government-funded deliverables itemized in Section 4.

A. Regulatory Planning

Pfizer will meet the necessary FDA requirements for conducting ongoing and planned clinical trials, and with its collaboration partner, BioNTech, will seek FDA approval or authorization for the vaccine, assuming the clinical data supports such application for approval or authorization. Given that these clinical trials are regulated by the FDA and HHS, there is no need for separate regulation by the U.S. Army Medical Research and Materiel Command. BioNTech is the Investigational New Drug ("IND") holder, while Pfizer is the designated agent for all interactions with the FDA and is taking the lead on all communications with and submissions to FDA.

B. Clinical and Regulatory Approach

BioNTech is the regulatory sponsor for trials of the vaccine and will be the applicant in the US for an EUA and/or a BLA, and will ultimately be the holder of any such approval issued in the US. Pfizer is BioNTech's authorized agent to FDA. As noted above, Pfizer is the designated agent for all interactions with the FDA and is taking the lead on all communications with and submissions to FDA.

Prior to commencing clinical development, on February 6, 2020, BioNTech obtained feedback from the Paul Ehrlich Institute ("PEI") on plans for rapid vaccine development in response to the COVID-19 outbreak following a Scientific Advice Meeting. Based on the PEI feedback, BioNTech refined the clinical program plan and prepared a detailed protocol for FIH clinical study (BNT162). Additionally, a meeting was held by BioNTech on February 24, 2020 with the Chinese CDC to discuss a possible Special Review Procedure.

In Germany, BioNTech began a Phase 1/2 study (BNT162-01) in late April 2020. BNT162-01 is a dose-escalation trial investigating the safety and immunogenicity of COVID-19 mRNA vaccine candidates in healthy adults. The primary objective of the study is to describe the safety and tolerability profiles of prophylactic BNT162 vaccine candidates after a single dose (for saRNA) or two doses separated by 21 days (uRNA and modRNA candidates). The secondary objective of the study is to describe the immune response to the vaccine in healthy adults, as measured by a functional antibody assay, such as virus neutralization.

Informed by BNT162-01, the Phase 1/2 US study (C4591001) of the vaccine candidates started in May 2020. Pfizer and BioNTech utilized this approach to efficiently optimize formulation and dose selection in the clinic. Study C4591001 is a single, multistage and multi-phase trial (including the pivotal efficacy portion) designed to generate the data needed to achieve FDA approval or authorization for use of one of the vaccine candidates. This is a randomized, placebo-controlled, observer-blind, dose-finding and vaccine candidate-selection study in healthy adults. The study is evaluating the safety, tolerability, and immunogenicity of the COVID-19 mRNA vaccine candidates.

The study consists of 3 stages:

Stage 1: to identify preferred vaccine candidate(s), dose level(s), number of doses, and schedule of administration (with the first 15 participants at each dose level of each vaccine candidate comprising a sentinel cohort);

Stage 2: an expanded-cohort stage; and

Stage 3: a final candidate/dose large-scale stage.

Using this approach, Pfizer and BioNTech are efficiently working towards selection of final candidate/dose level.

The study currently is being amended to incorporate a pivotal efficacy study design. Therefore, the study would be converted to a single Phase 1/2/3 study. The pivotal study portion (*i.e.*, Phase 2b/3) is expected to enroll up to ~30,000 subjects (1:1 randomized between vaccine and placebo).

Upon gathering adequate safety and immunogenicity/efficacy data in a sufficient number of subjects, Pfizer believes the vaccine candidate could, with FDA's agreement, be administered under EUA.

As background, Pfizer's and BioNTech's activities to ensure provision of vaccine on a timely schedule may include the following discrete activities, depending on emerging data and regulatory guidance.

Activity	Success Criteria	Estimated Timing
Candidate, dose, and regimen selection	Decision endorsed by Pfizer-BioNTech Joint Steering Committee	(b) (4)
Phase 2b/3 Study Start	Requires FDA (CBER) approval	(b) (4)
Phase 1/2/3 Demonstration of immunogenicity, efficacy (interim analysis) and safety	Adequate efficacy and safety data supports EUA application	(b) (4)
EUA Submission to Support Use in American Population	Acceptance of EUA submission	(b) (4)
BLA Submission to Support Use in American Population	Agreement from FDA (CBER) that proposed licensure package (preclinical, clinical, CMC) is acceptable	(b) (4)
EUA Issuance to Support Use in American Population	EUA issued	(b) (4)
BLA Approval to Support Use in American Population	BLA approval	(b) (4)
Post-Approval Commitments Agreed	Agreement with FDA	(b) (4)

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C. Chemistry Manufacturing Controls (CMC)

Pfizer will complete the necessary CMC and scale-up activities to demonstrate the ability to manufacture 100M doses (b) (4). Pfizer will use diligent efforts to manufacture and quality release (using Pfizer's quality system) 100M doses within the US in a non-preservative multi-dose vial (b) (4).

Pfizer currently estimates potential production rates (b) (4). With GMP production expected to commence (b) (4) for drug product, this plan would allow for ~40M doses to be supplied under this Statement of Work in (b) (4). As Pfizer validates the facilities and makes continuous process improvements, Pfizer currently anticipates such production rate to increase starting in (b) (4). Should clinical data indicate that a lesser amount of dosage may be needed, there could be an increase in the anticipated potential number of doses supplied in (b) (4).

As background, to help ensure delivery of the doses, Pfizer is undertaking the following CMC activities:

1. Continue with BioNTech to manufacture initial clinical trial material for EU and US Phase 1/2/3 studies, through mRNA production in Germany and EU (Puurs, Belgium for fill-finish) and drug product/labelling operations at EU CMOs and establish EU based supply chain for lipid nanoparticle (LNP) formulation, fill, finish and distribution for commercial supply.

2. Complete knowledge transfer of the technology and manufacturing process from BioNTech (and its CMO partners) to Pfizer in order to establish the process at Pfizer in the US, (b) (4)

3. Obtain all raw material supplies for manufacturing. This may include support of existing third-party suppliers of raw materials, qualifying new third-party suppliers and/or in-house production of certain raw materials, (b) (4)

4. Establish (b) (4) mRNA (drug substance), lipid nanoparticle (LNP) formulation/fill finish (drug product) capacity for GMP Covid-19 pandemic supply of the RNA-based COVID-19 vaccine on US soil.

5. Develop the shipping model for the -80 °C drug product in consultation with CDC.

In parallel, Pfizer is prepared to also evaluate alternative options including:

1. Conduct necessary stability and development studies to establish (b) (4)

2. Conduct necessary formulation and stability studies to develop (b) (4)

The CMC program may include, but not be limited to: (a) (b) (4); (b) drug substance development; (c) drug product development (LNP formulation, fill-finish); (d) analytical development in GLP and GMP setting; (e) GLP and GMP manufacturing; and (f) and shipping of -80 °C frozen product.

(a) (b) (4)

(b) Drug Substance Development: Pfizer shall scale-up its capabilities for process optimization, manufacture, analysis, release of GMP materials (mRNA) and securing necessary raw materials from third party providers. For drug substance manufacture, Pfizer seeks to build-out the existing purification suite located at Pfizer's (b) (4)

Pfizer shall supply incremental resources to transfer/implement new technology and GMP manufacturing processes, including technical experts, quality professionals, analytical technicians, and trained operational staff.

(c) Drug Product Development (Lipid Nanoparticle (LNP Formulation, Fill-Finish)): Activities Pfizer shall perform may include, but are not be limited to, securing of necessary lipids for formulation and manufacturing process development for BNT162; defining the formulation; and initial development of manufacturing process and analytical methods. Pfizer will undertake to (b) (4)

(d) Analytical Development: Analytical development may include, but not be limited to: methods transfer participation at receiving site and in-process testing support; process verification on commercial equipment; media fill runs; engineering trials; registration batch manufacture; and registration batch stability (pivotal stability) testing. (b) (4)

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(e) GLP and GMP Manufacturing: Packaging, storage and distribution of clinical trial supplies for Phase 1/2 will be conducted by (b) (4)

(f) Shipping of -80 °C frozen product: Pfizer is evaluating extension of current clinical packaging configuration using soft boxes and dry ice. (b) (4)

As background, to maintain a timely completion schedule of the vaccine, Pfizer is aspiring to undertake the following discrete activities, without Government funding:

(b) (4)

1.2 Scope

The scope of this prototype project is the demonstration by Pfizer of the supply and logistics capability to manufacture and distribute to the Government of 100M doses of a novel mRNA-based vaccine that has received FDA-approval or authorization based on demonstration of efficacy (hereafter FDA-approved or authorized). The criteria for successful Emergency Use Authorization (EUA) are described in *Emergency Use Authorization of Medical Products and Related Authorities: Guidance for Industry and Other Stakeholders, January 2017*; and *Development and Licensure of Vaccine to Prevent COVID-19: Guidance for Industry June 2020*. The successful provision of these doses shall establish the effectiveness of a technology capable of potentially providing immediate and long-term solutions to coronavirus infections. While pre-clinical, clinical, and chemistry/manufacturing/controls (CMC) activities are described in the Background section of this Statement of Work, the Parties acknowledge and agree that such activities not related to the large-scale manufacturing demonstration are out-of-scope for this prototype project as Pfizer and BioNTech have and will continue to fund these activities, without the use of Government funding.

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1.3 Objective

(a) Prototype Project

As set forth more fully in Section 11.7, the provisions of this Section 1.3 hereby supersede and replace, in their entirety, the provisions of Section 21.15 of the MCDC Base Agreement, 2020-532 (July 2018) (“Base Agreement”).

Consistent with the Government’s objectives under Operation Warp Speed, Pfizer intends to employ its proprietary manufacturing technology and processes, in a manner compliant with applicable laws and regulations, including 21 CFR 210 and 211 and the Drug Supply Chain Security Act (to the extent required for COVID-19 medical countermeasures, as defined by relevant FDA guidance), to manufacture and deliver vaccine. Success of the prototype project is defined as manufacture of 100M doses of Pfizer and BioNTech’s mRNA-based COVID-19 vaccine and, upon FDA-approval or authorization as described above, delivery of those doses in accordance with Section 6.0.

This effort constitutes a prototype project because it will be used to evaluate the technical feasibility of completion of the prototype project during the ongoing COVID-19 pandemic and unprecedented threats to several components of the prototype project. In addition, this is a prototype project because Pfizer will demonstrate and prove-out the at-scale, multi-lot proprietary manufacturing activities in order to assess the feasibility to support the necessary quantity of safe and effective doses required for vaccination of the U.S. population and deliver those doses within challenging cold chain requirements in accordance with Section 6.0. Successful completion of the prototype project will demonstrate Pfizer’s capability to (i) rapidly manufacture product, which can be further scaled-up to meet mutually agreed to surge requirements with limited advance notification and (ii) distribute large quantities of the FDA-approved or authorized drug product in accordance with Section 6.0. For clarity, any manufacturing and delivery of drug product in excess of the specific quantities set forth in Section 4.0 of this Statement of Work, shall be subject to a separate mutually acceptable production agreement between Pfizer and the Government.

(b) Follow-On Production Contract/Options

In accordance with 10.U.S.C. § 2371b(f), and upon a determination that the prototype project is successful, or at the accomplishment of particularly favorable or unexpected results that would justify transition to production, the Government and Pfizer may enter into a non-competitive, mutually-acceptable, follow-on production agreement for additional manufacturing of the vaccine without the use of competitive procedures, which agreement shall reflect an unfunded option on the basis set forth in the following paragraph (the “Option”).

Under the Option, the Government may request that Pfizer produce and deliver up to 500M additional doses for purchase by the Government for delivery (b) (4)

Any order placed pursuant to the Option Agreement will provide for a

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minimum of 100M doses, provided that the aggregate number of doses ordered under the Option shall not exceed 500M.

Upon any request pursuant to the Option, Pfizer shall inform the Government of appropriate lead times based on purchase of raw materials, capacity reservation and other factors, and Pfizer and the Government shall mutually agree on an appropriate estimated delivery schedule. Each order under the Option will be subject to the reasonable acceptance of Pfizer, it being understood that Pfizer shall have no obligation to accept any order pursuant to the Option that would involve (b) (4)

As promptly as practicable following the effective date of this Agreement, the Government and Pfizer will agree in principle upon a form of production agreement reflecting the Option that can be executed as a binding agreement promptly upon Government request following such determination, demonstration, or accomplishment.

2.0 APPLICABLE REFERENCES

Current Good Manufacturing Procedures, 21 CFR 210 and 211.

3.0 REQUIREMENTS

Pfizer shall conduct manufacturing activities to support production and distribution of vaccine doses after the final vaccine candidate from its development program is selected (currently expected to occur in July 2020). Subject to the terms and conditions of this Agreement, including without limitation Sections 3.1, 6.0, 11.5 and 11.6, Pfizer shall use diligent efforts to manufacture, quality release (using Pfizer's quality system), and deliver 100M doses of an FDA-approved or authorized vaccine in a preservative-free, multi-dose vial no later than the end of the period of performance (as defined in Section 3.1).

Pfizer anticipates providing the vaccine, subject to FDA approval or authorization, as -80 °C frozen product that needs to be maintained at or below that temperature prior to dosing. The Government acknowledges that Pfizer's responsibility for cold chain will cease upon delivery in accordance with Section 6.0.

Pfizer anticipates providing the vaccine, subject to FDA-approval or authorization, as a concentrate that needs to be diluted at point of use prior to dosing. Vaccinators will need to use locally sourced 0.9% Sodium Chloride Injection, USP (Normal Saline), syringes and needles.

3.1 Period of Performance

The total proposed duration of this prototype initiative is (b) (4) with an expected completion date (b) (4) (the "period of performance"). If FDA-approval or authorization is not issued by October 31, 2020

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as estimated in Section 1.1.2 above, and Pfizer expects it will be unable to timely complete performance, then the Parties will discuss in good faith a contract modification to shift forward the estimated delivery schedule to reflect the difference in time period between October 31, 2020 and the date of actual regulatory approval or authorization.

As a result of these discussions, the Government shall have the unilateral ability to extend the Period of Performance of this prototype project in increments of up to thirty (30) days at a time. In no event can this unilateral right to extend the period of performance require performance (b) (4) or result in a requirement for Pfizer to demonstrate the ability to manufacture more than 100M doses.

Notwithstanding the efforts and estimated dates set forth throughout this Statement of Work, and as set out more fully in Sections 11.5 and 11.6, both Parties recognize that the vaccine is currently in Phase 1/2 clinical trials and that, despite the diligent efforts of Pfizer and BioNTech in research, and development and manufacturing, the prototype project may not be successful due to technical, clinical, regulatory or manufacturing challenges or failures.

3.2 Management and Reporting

As set forth more fully in Section 11.7, the provisions of this Section 3.2 hereby supersede and replace, in their entirety, Section 1.05 of the Base Agreement.

Pfizer will not employ any new or other Project Management components and Pfizer shall have no obligation to provide any custom reports to the Government except as provided herein. The Government acknowledges that Pfizer plans to utilize existing Pfizer-formatted reports to provide this information to the Government as described in the Deliverable table below at Section 4.0.

Pfizer shall provide (b) (4) technical reports providing an update of relevant ongoing non-Government funded activities.

Pfizer shall provide, (b) (4) a synopsis of the Phase 2b/3 clinical trial protocol, which synopsis shall include [Overview of the Protocol, Objectives and Endpoints, Statistical Methods, and Schedule of Activities].

Pfizer shall provide copies of EUA and BLA filings, as well as interim and final data updates from clinical studies in a format determined by Pfizer.

Pfizer shall provide weekly prototype production status reports, including the number of batches produced, doses in the batch, and release status of the finished doses.

In addition to regular reporting requirements, during the period of performance, Pfizer shall use diligent efforts to notify the Government (b) (4) of any event, risk, formal or informal

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FDA communication, or other issue that would be reasonably expected to materially change the anticipated schedule by one week or more.

Except for reports expressly contemplated in this Statement of Work, Pfizer and the Government agree that Pfizer will not be subject to any reporting requirements contemplated in Section 1.05 of the Base Agreement.

4.0 DELIVERABLES

As set forth more fully in Sections 11.5 and 11.6, the Government understands that the dates set forth below are Pfizer's best estimate, as of the Execution Date of this Agreement, of its development and manufacturing timelines, and that these timeframes are subject to significant risks and uncertainties. Pfizer will promptly notify the Government of any event(s) that would be reasonably expected to materially alter projected Estimated Due Date for Deliverables 4.1 through 4.20.

The Government agrees that it will not resell any of the deliverables to any third party.

Deliverables

Del. #	Deliverable Description	Estimated Due Date	Format	SOW Reference	Government Role	Data Rights
4.1	Project Kick-Off materials	(b) (4)	Telecon. and related slides	--	Review	(b) (4)
4.2	Phase 2b/3 Clinical Trial Synopsis	(b) (4)	Pfizer-determined format	(b) (4)	Review	(b) (4)
4.3	Provision of PL 115-92 Sponsor Authorization Letter	(b) (4)	--	--	Review/Approve	(b) (4)
4.4	(b) (4) Updates on Prototype Production Status	(b) (4)	Pfizer-determined format	(b) (4)	Review	(b) (4)
4.5	(b) (4) Business and Technical Report	(b) (4)	Pfizer-determined format	(b) (4)	Review	(b) (4)

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4.6	EUA Filing	(b) (4)	Pfizer-determined format	(b) (4)	Review	(b) (4)
4.7	BLA Filing	(b) (4)	Pfizer-determined format	(b) (4)	Review	(b) (4)
4.8	Delivery of 100M doses	(b) (4)	--	(b) (4)	Receipt	(b) (4)
4.9	Release documentation for delivered doses	(b) (4)	Pfizer-determined format	(b) (4)	Review	(b) (4)
4.10	Supply Chain Resiliency Plan or Pfizer Equivalent	(b) (4)	Pfizer-determined format	(b) (4)	Review & Comment	(b) (4)
4.11	Manufacturing Data Requirement or Pfizer Equivalent	(b) (4)	Pfizer - determined format	(b) (4)	Review & Comment	(b) (4)
4.12	Product Development Source Material & Manufacturing Reports and Projections	(b) (4)	Pfizer-determined format	(b) (4)	Review & Comment	(b) (4)
4.13	Work Location Report or Pfizer Equivalent	(b) (4)	Pfizer-determined format	(b) (4)	Review & Comment	(b) (4)
4.14	Facility Security Plan or Pfizer Equivalent	(b) (4)	Pfizer-determined format	(b) (4)	Review & Comment	(b) (4)
4.15	Confirmation of Registration and Listing with FDA	(b) (4)		(b) (4)	Review	(b) (4)

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4.16	Formal Written Responses from the FDA	(b) (4)	(b) (4)	Review	(b) (4)
4.17	FDA Inspection and Compliance Notices, Observations and Responses	(b) (4)	(b) (4)	Review	(b) (4)
4.18	Manufacturing Development Plan*	(b) (4)	(b) (4)	Review	(b) (4)
4.19	Quality Management Plan**	(b) (4)	(b) (4)	Review	(b) (4)
4.20	Shipping Specifications and Details	(b) (4)	(b) (4)	Review	(b) (4)

* Manufacturing Development Plan. Pfizer will, (b) (4)

describe the manufacturing process for the vaccine product to ensure conformity with §501(a)(2)(B) of the Food, Drug, and Cosmetics Act (FD&C Act, Title 21 United States Code (“U.S.C.”) §351 (a)(2)(B)), regarding good manufacturing practices (“GMP”). This plan shall describe (b) (4)

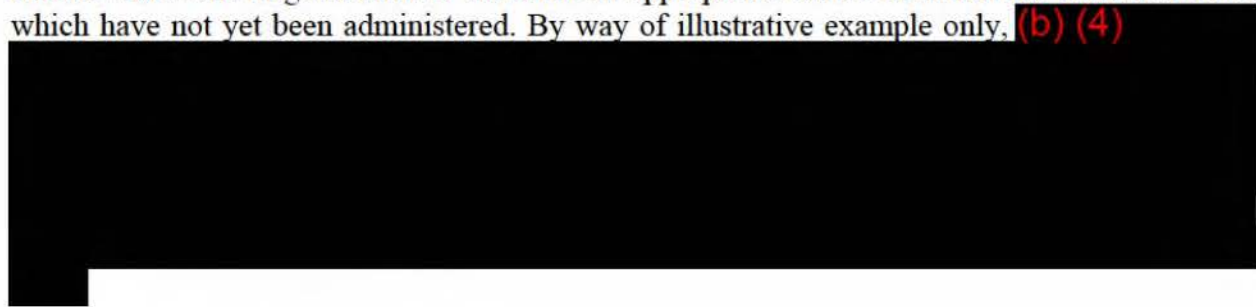
** Quality Management Plan. Pfizer will, (b) (4)

provide a quality management plan (b) (4)

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Except as contemplated by the Option, the price per dose set forth in this Statement of Work is provided in connection with Operation Warp Speed and this specific Statement of Work only. This price shall not serve as the basis for pricing under any separate government contracts between Pfizer and HHS, the Department of Defense, or any other Department or agency of the Government by application of most favored customer, most favored nations, or any other contract or program-specific terms.

For clarity, the Government will have no right to withhold payment in respect of any delivered doses, unless the FDA has withdrawn approval or authorization of the vaccine. In such event, the Parties will work in good faith to establish an appropriate course of action for delivered doses which have not yet been administered. By way of illustrative example only, (b) (4)



6.0 SHIPPING PROVISIONS

In coordination with the Government, Pfizer will conduct a demonstration of the shipping process prior to the first delivery of doses at a time mutually agreed by the Parties. As set forth in Section 4.0, Pfizer agrees to share specifications and details associated with the shipping process and containers to enable the Government to adequately plan and prepare for potential distribution of the vaccine.

Pfizer will notify the Government the date by which doses will become available for delivery. The Government will confirm dosage orders by ship-to location (b) (4) in advance of those dates; *provided* that each such ship-to location will abide by the specifications provided by Pfizer or will otherwise be agreed by Pfizer and the Government. The number of ship-to locations and the manner of delivery shall be identified to create an efficient delivery of the doses, subject to mutual agreement of the parties. The recommended delivery quantity for each ship-to location is (b) (4)



(b) (4)



7.0 INTELLECTUAL PROPERTY, DATA RIGHTS, AND COPYRIGHTS

As set forth more fully in Section 11.7, the provisions of this Section 7.0 supersede and replace, in their entirety, the provisions of Article X (Patent Rights), Article XI (Data Rights) of the Base Agreement.

7.1 Inventions

As between Pfizer and the Government, Pfizer shall hereby retain all of its rights, titles and interests in and to any and all inventions conceived and reduced to practice by Pfizer and/or BioNTech (i) as of the Effective Date of this Agreement, or (ii) after the Effective Date of this Agreement, outside the scope of this Statement of Work (“Background Inventions”). Pfizer does not grant to the Government any license to practice the Background Inventions under this Agreement.

As between Pfizer and the Government, all inventions conceived or first actually reduced to practice in the performance of this Statement of Work (“Subject Inventions”) shall be owned by Pfizer. If invented solely by Pfizer, Pfizer will be able to elect, in its discretion, whether to hold Subject Inventions as trade secrets, and holding a Subject Invention as a trade secret will not forfeit title to the Government. Pfizer does not grant to the Government a license to practice any Subject Inventions on behalf of the Government.

Notwithstanding the foregoing, and as set forth more fully in Section 1.1.2, the Government acknowledges that it is not funding the research or development of the vaccine, or CMC/process development in respect thereof. As such, neither Pfizer nor the Government anticipate the conception or reduction to practice of any Subject Inventions.

The Government acknowledges that the Bayh-Dole Act does not apply to or govern this Agreement. Given that the Government will not fund the conception or reduction to practice of Background Inventions or Subject Inventions hereunder, this Agreement shall neither (i) give the Government any rights to “march-in,” as that term is defined in 35 U.S.C. § 203, nor (ii) subject Pfizer to the manufacturing requirements of 35 U.S.C. § 204.

7.2 Data

The Government recognizes that all data relating to the vaccine has been and will continue to be generated by Pfizer and its collaboration partner, BioNTech, without the use of Government funding.

As between Pfizer and the Government, Pfizer shall own any and all data generated by Pfizer and/or BioNTech (i) as of the Effective Date of this Statement of Work, or (ii) after the Effective Date of this Statement of Work, outside the scope of this Statement of Work (“Background Data”). As between Pfizer and the Government, Pfizer also shall own any and all data generated by Pfizer

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within the scope of this Statement of Work ("Subject Data"). For the avoidance of doubt, the parties do not anticipate Pfizer generating any Subject Data using Government funding.

Pfizer hereby grants the Government a non-exclusive license to use any Background Data and Subject Data contained in the deliverables pursuant to Section 4, but solely to the extent necessary for the Government to perform its obligations under this Agreement and arrange administration of the doses delivered in accordance with FDA and other applicable regulations.

The Government will provide Pfizer with no less than thirty (30) days' written notice prior to releasing, in response to a Freedom of Information Act (FOIA) request, any document submitted by Pfizer to Government. During this 30-day period, Pfizer shall have the right to notify Government which documents, if any, contain trade secrets of Pfizer, BioNTech or their respective collaboration partners (or other information legally withholdable from release under FOIA).

7.3 Regulatory Rights

Pfizer will seek and anticipates that it will achieve FDA-approval or authorization and commercialization of Pfizer and BioNTech's mRNA-based Vaccine against SARS-CoV-2 Coronavirus (the "Technology").

Pfizer and the Government agree to the following:

Communications. Pfizer will provide the Government with all formal written responses from the FDA regarding the Technology (b) (4).

Pfizer also shall use diligent efforts to provide to the USG Government any and all FDA inspection and compliance notices, observations, and responses from Pfizer (b) (4). The Government shall limit distribution of these documents to HHS and DoD regulatory personnel, and may share the substance of the documents to others within the DoD and HHS that have a need to know.

DoD Medical Product Priority. PL 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. Pfizer recognizes that only the DoD can utilize PL 115-92. (b) (4)

Pfizer shall submit Public Law 115-92 Sponsor Authorization Letter that will be delivered to the designated OWS POC(s) (b) (4).

8.0 SECURITY / EXPORT CONTROL

As set forth more fully in Section 11.7, the provisions of this Section 8 supersede the provisions of Article XII (Export Controls). The following requirements of Article XVII (Security and

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OPSEC) of the Base Agreement are not applicable and are therefore self-deleting and replaced by this Section: all references to CUI and CDI, sub-paragraphs (1) through (20) excepting sub-Paragraphs (3)(e), (4), and (20)(d).

The security classification for this effort is Unclassified. As it is currently not anticipated that any Controlled Unclassified Information (“CUI”) will be obtained under this Statement of Work, other than Pfizer proprietary information, DFARS 252.204-8012 shall not apply. In addition, the training requirements of Article XVII of the Base Agreement shall not apply. However, if CUI is provided, Pfizer will keep all such information confidential and will only give access to such information to persons with a legitimate need for such access.

Pfizer agrees to comply with all applicable laws regarding commodities and technology subject to this Statement of Work. Pfizer will submit plans and reports as set forth in Section 4.0 above addressing the security topics generally contemplated by Appendix 1 to this Statement of Work. The Government acknowledges that these plans will reflect Pfizer’s established security procedures in place with respect to its facilities and information security, which are at least as protective as would be customary for a global company. Pfizer will use commercially reasonable efforts to implement any further procedures/precautions reasonably requested by the Government with respect to Statement of Work and Appendix 1, at Pfizer’s sole discretion and as long as such implementation would not adversely impact Pfizer’s ordinary operation of its facilities and systems in connection with its other business and products.

9.0 MISCELLANEOUS REQUIREMENTS (SAFETY, ENVIRONMENTAL, ETC.)

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10.0 GOVERNMENT FURNISHED PROPERTY/MATERIAL/INFORMATION

As set forth more fully in Section 11.7, the provisions of this Section 10.0 supersede and replace, in their entirety, the provisions of Article XIII (Title and Disposition of Property) of the Base Agreement.

There will be no Government furnished equipment, and no equipment will be funded by the Government under this Statement of Work.

11.0 OTHER

11.1 PREP Act.

In accordance with the Public Readiness and Emergency Preparedness Act (“PREP Act”), Pub. L. No. 109-148, Division C, Section 2, as amended (codified at 42 U.S.C. § 247d-6d and 42 U.S.C. § 247d-6e), as well as the Secretary of HHS’s Declaration Under the Public Readiness and

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Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15198 (Mar. 17, 2020, effective Feb. 4, 2020), and amended on April 15, 2020, 85 Fed. Reg. 21012, and on June 8, 2020, 85 Fed. Reg. 34740 (together, the “Prep Act Declaration”):

- (i) This Agreement is being entered into for purposes of facilitating the manufacture, testing, development, distribution, administration, and use of “Covered Countermeasures” for responding to the COVID-19 public health emergency, in accordance with Section VI of the PREP Act Declaration;
- (ii) Pfizer’s performance of this Agreement falls within the scope of the “Recommended Activities” for responding to the COVID-19 public health emergency in accordance with Section III of the PREP Act Declaration; and
- (iii) Pfizer is a “Covered Person” per Section V of the PREP Act Declaration.

Therefore, in accordance with Sections IV and VII of the PREP Act Declaration as well as the PREP Act (42 U.S.C. § 247d-6d), the Department of Defense contracting via assisted acquisition on behalf of the HHS, expressly acknowledges and agrees that the HHS Declaration cited above, specifically its language providing immunity from suit and liability is applicable to this Agreement, as long as Pfizer’s activities fall within the terms and conditions of the PREP Act and the PREP Act Declaration.

The Government may not use, or authorize the use of, any products or materials provided under this Agreement, unless such use occurs in the United States and is protected from liability under a declaration issued under the PREP Act, or a successor COVID-19 PREP Act declaration of equal or greater scope.

11.2 Terminations. As set forth more fully in Section 11.7, the provisions of this Section 11.2 hereby supersede and replace, in their entirety, Sections 2.03 and 2.06 of the Base Agreement:

(a) (b) (4)



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(b) Stop-Work Orders. Except as required by applicable law or regulation, or judicial or administrative order, the Government shall not have the authority to issue a Stop-Work Order to halt the work contemplated under this Statement of Work.

(c) Consequences of Termination. In the event of termination of this Agreement pursuant to this Section 11.2, or expiration of this Agreement at the end of the period of performance as set forth in Section 3.1, this Agreement shall forthwith become null and void and have no effect, without any liability on the part of any Party; *provided, however*, that Sections 7, 11 and 12 hereof, and Article VIII (Confidential Information) of the Base Agreement, shall survive any termination or expiration of this Agreement; and *provided, further*, that the termination or expiration of this Agreement shall not release any Party hereto of any liability, including any outstanding payments of the Government for doses previously delivered hereunder, which at the time of termination or expiration had already accrued to the other party in respect to any act or omission prior thereto.

11.3 Audits. As set forth more fully in Section 11.7, the provisions of this Section 11.3 hereby supersede and replace, in their entirety, the provisions of Section 5.07 (Financial Records and Reports) of the Base Agreement.

Pfizer's relevant financial records shall not be subject to audit until the Government has provided funds to Pfizer. These records will be subject to audit for a period not to exceed three (3) years after final payment under this Agreement. Pfizer shall have the right to request use of a third-party audit firm to audit Pfizer's books and records maintained in connection with this Agreement; however, in accordance with 10 U.S.C. § 2371b(c) for a period not to exceed three (3) years after final payment under this Agreement, the Comptroller General shall have access to examine the records of any party to the agreement or any entity that participates in the performance of the agreement.

11.4 Disputes. As set forth more fully in Section 11.7, Section 7.02 of the Base Agreement is hereby amended to add the following at the end of said section:

The Government's breach of this Statement of Work may result in money damages and nothing in the Project Agreement (if any) or Base Agreement prevents Pfizer from seeking relief in the United States Court of Federal Claims pursuant to 28 U.S.C. § 1491.

11.5 Timing Estimates. All timing estimates set forth in this Statement of Work are subject to change based on emerging data, regulatory guidance, and manufacturing and technical developments, among other risks.

11.6 Limitation of Liability. The Government acknowledges and agrees that Pfizer's efforts to develop and manufacture a vaccine intended to prevent COVID-19 disease caused by SARS-CoV-2 are aspirational in nature and subject to significant risks and uncertainties. Accordingly, notwithstanding anything to the contrary in this Statement of Work or the Base Agreement, Pfizer shall have no liability for any failure to develop, obtain or maintain U.S. regulatory approval or authorization of such a vaccine in accordance with the estimated schedule described in this Statement of Work.

Even if a vaccine is successfully developed and obtains U.S. regulatory approval or authorization, Pfizer shall have no liability for any failure to deliver doses in accordance with the estimated delivery dates set forth in this Statement of Work to the extent any such change in delivery dates is based on emerging data, regulatory guidance, manufacturing and technical developments, or other risks outside Pfizer's control; *provided, however*, Government retains the right to terminate this Agreement or to issue a Stop-Work Order, as specifically contemplated in Sections 11.2(1) and 11.2(b).

(b) (4)

. This Section 11.6 supersedes the Base Agreement's other liability provisions solely to the extent they are inconsistent with this Statement of Work.

11.7 Order of Precedence. Notwithstanding the provisions of Article XXIII (Order of Precedence) of the Base Agreement, the Parties hereby expressly agree that to the extent any provision of the Project Agreement (if any) or this Statement of Work conflicts with any provision of the Base Agreement, the provision of the Project Agreement (if any) or this Statement of Work, as applicable, shall supersede and replace, in the entirety, the conflicting provision of the Base Agreement and control the relationship of the Parties.

Without limiting the generality of the foregoing, this Section 11.7 shall supersede Article XXIII (Order of Precedence) of the Base Agreement and the terms of this Statement of Work shall constitute "specifically negotiated Project Agreement terms" referenced in the last sentence thereof.

This Statement of Work hereby supersedes, without limitation, the following provisions of the Base Agreement: Section 1.05 (Reporting Requirements), Section 2.03 (Termination Provisions), Section 2.06 (Stop-Work), Section 5.07 (Financial Records and Reports), Section 8.05 (Term), Article IX (Publications), Article X (Patent Rights), Article XI (Data Rights), XII (Export Controls), Article XIII (Title and Disposition of Property), Article XVII (Security and OPSEC), and Sections 21.6-21.15 (Regulations) and the integration clause above the signature block to the Base Agreement.

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11.8 (b) (4)

11.9 Non-Traditional Defense Contractor. Pfizer has self-certified that Pfizer meets the definition of a “Nontraditional Defense Contractor” as defined in the Base Agreement and therefore is not subject to the cost-sharing requirement referenced in Article VI of the Base Agreement.

11.10 Confidentiality. As set forth more fully in Section 11.7, the provisions of this Section 11.10 hereby supersede and replace, in their entirety, the provisions of Section 8.05 of the Base Agreement.

The obligations of the Receiving Party under this Section shall continue for a period of ten (10) years from the conveyance of Confidential Information. If Pfizer shall need to disclose trade secret information to the Government, Pfizer and the Government will first determine in good faith whether the Government desires to receive any such trade secret information and if the Government so desires to receive such trade secret information, all such information shall be held by the Government in confidence in perpetuity.

11.11 Announcements. Neither Pfizer nor the Government shall make, or permit any person to make, any public announcement concerning the existence, subject matter or terms of this Agreement, the transactions contemplated by it, or the relationship between the Pfizer and the Government hereunder, without the prior written consent of the other, such consent not to be unreasonably withheld or delayed, except as required by law, any governmental or regulatory authority (including, without limitation, any relevant securities exchange), any court or other authority of competent jurisdiction. Notwithstanding the foregoing, Pfizer and (its collaboration partners) shall have the right, but not the obligation, to prepare and submit scientific publications and release information to the public about its Covid-19 development program, without the Government’s consent or involvement. This section supersedes and replaces Article IX of the Base Agreement.

12.0 AGREEMENTS OFFICER’S REPRESENTATIVE (AOR) AND ALTERNATE AOR CONTACT INFORMATION

AOR

NAME: (b) (6)

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MAILING ADDRESS:

EMAIL: (b) (6)

PHONE: (b) (6)

AGENCY NAME/DIVISION/SECTION: BARDA/ASPR/HHS

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Appendix 1: Clause for MCDC Consortium Other Transaction Authority Agreements

Standard Language OWS for Consortium OTA

Required MCDC Base Agreement Modifications

The Medical CBRN Consortium (MCDC) Base Agreement, Article XVII, SECURITY & OPSEC shall apply to this Project Agreement. In addition, the below language shall replace Paragraph 6 of Article XVII of the MCDC Base Agreement.

(6) Access and General Protection/Security Policy and Procedures. This standard language text is applicable to ALL PAH employees working on critical program information or covered defense information related to Operation Warp Speed (OWS), and to those with an area of performance within an Army controlled installation, facility or area. PAH employees shall comply with applicable installation, facility and area commander installation/facility access and local security policies and procedures (provided by government representative). The PAH also shall provide all information required for background checks necessary to access critical program information or covered defense information related to OWS, and to meet installation access requirements to be accomplished by installation Provost Marshal Office, Director of Emergency Services or Security Office. The PAH workforce must comply with all personal identity verification requirements as directed by DOD, HQDA and/or local policy. In addition to the changes otherwise authorized by the changes clause of this agreement, should the Force Protection Condition (FPCON) at any individual facility or installation change, the Government may require changes in PAH security matters or processes.

Required SOW Language for Deliverables (in body of SOW or Deliverables Section)

Information Security

Classification guidance for Operation Warp Speed - The security level for this agreement is UNCLASSIFIED.

“Controlled technical information,” “covered contractor information system,” “covered defense information,” “cyber incident,” “information system,” and “technical information” are defined in DFARS Clause 252.204-7012, Safeguarding Covered Defense Information and Cyber Incident Reporting.

Personnel Security

In addition to the industry standards for employment background checks, The Contractor must be willing to have key individuals, in exceptionally sensitive positions, identified for additional vetting by the United States Government.

Supply Chain Resiliency Plan

The contractor shall develop and submit within 30 calendar days after contract award, a comprehensive Supply Chain Resiliency Program that provides identification and reporting of critical components associated with the secure supply of drug substance, drug product, and work-in-process through to finished goods.

- a) A critical component is defined as any material that is essential to the product or the manufacturing process associated with that product. Included in the definition are consumables and disposables associated with manufacturing. NOT included in the definition are facility and capital equipment.

Consideration of critical components includes the evaluation and potential impact of raw materials, excipients, active ingredients, substances, pieces, parts, software, firmware, labeling, assembly, testing, analytical and environmental componentry, reagents, or utility materials which are used in the manufacturing of a drug, cell banks, seed stocks, devices and key processing components and equipment. A clear example of a critical component is one where a sole supplier is utilized.

The contractor shall identify key equipment suppliers, their locations, local resources, and the associated control processes at the time of award. This document shall address planning and scheduling for active pharmaceutical ingredients, upstream, downstream, component assembly, finished drug product and delivery events as necessary for the delivery of product.

- a) Communication for these requirements shall be updated as part of an annual review, or as necessary, as part of regular contractual communications.
- b) For upstream and downstream processing, both single-use and re-usable in-place processing equipment, and manufacturing disposables also shall be addressed. For finished goods, the inspection, labeling, packaging, and associated machinery shall be addressed taking into account capacity capabilities.
- c) The focus on the aspects of resiliency shall be on critical components and aspects of complying with the contractual delivery schedule. Delivery methods shall be addressed, inclusive of items that are foreign-sourced, both high and low volume, which would significantly affect throughput and adherence to the contractually agreed deliveries.

The contractor shall articulate in the plan, the methodology for inventory control, production planning, scheduling processes and ordering mechanisms, as part of those agreed deliveries.

- a) Production rates and lead times shall be understood and communicated to the Contracting/Agreement Officer or the Contracting/Agreement Officer's Representative as necessary.
- b) Production throughput critical constraints should be well understood by activity and by design, and communicated to contractual personnel. As necessary, communication should focus on identification, exploitation, elevation, and secondary constraints of throughput, as appropriate.

Reports for critical items should include the following information:

- a) Critical Material
- b) Vendor
- c) Supplier, Manufacturing / Distribution Location
- d) Supplier Lead Time
- e) Shelf Life
- f) Transportation / Shipping restrictions

The CO and COR reserve the right to request un-redacted copies of technical documents, during the period of performance, for distribution within the Government. Documents shall be provided within ten (10) days after CO issues the request. The Contractor may arrange for additional time if deemed necessary, and agreed to by the CO.

Manufacturing Data Requirements:

The Contractor shall submit within 30 calendar days after award detailed data regarding project materials, sources, and manufacturing sites, including but not limited to: physical locations of sources of raw and processed material by type of material; location and nature of work performed at manufacturing, processing, and fill/finish sites; and location and nature of non-clinical and clinical studies sites. The Government may provide a table in tabular format for Contractor to be used to submit such data which would include but not be limited to the following:

- Storage/inventory of ancillary materials (vials, needles, syringes, etc.)
- Shipment of ancillary materials (vials, needles, syringes, etc.)
- Disposal of ancillary materials (vials, needles, syringes, etc.)
- Seed development or other starting material manufacturing
- Bulk drug substance and/or adjuvant production
- Fill, finish, and release of product or adjuvant
- Storage/inventory of starting materials, bulk substance, or filled/final product or adjuvant
- Stability information of bulk substance and/or finished product
- Shipment of bulk substance of final product
- Disposal of bulk substance or final product

Product Development Source Material and Manufacturing Reports and Projections:

The Contractor shall submit a detailed spreadsheet regarding critical project materials that are sourced from a location other than the United States, sources, and manufacturing sites, including but not limited to: physical locations of sources of raw and processed material by type of material; location and nature of work performed at manufacturing sites; and location and nature of non-clinical and clinical study sites.

The Contractor will provide manufacturing reports and manufacturing dose tracking projections/actuals utilizing the “COVID-19 Dose Tracking Templates”, on any contract/agreement that is manufacturing product

- Contractor will submit Product Development Source Material Report
 - Within month of contract award
 - Within 30 days of substantive changes are made to sources and/or materials
 - Or on the 6th month contract anniversary.
- Contractor will update the Dose Tracking Template weekly, during manufacturing campaigns and COVID response, with the first deliverable submission within 15 days of award/modification
- The Government will provide written comments to the Product Development Source Material and Manufacturing Report within 15 business days after the submission
- If corrective action is recommended, Contractor must address all concerns raised by the Government in writing

Contractor Locations:

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

Contractor will submit Work Locations Report:

- Within 5 business days of contract 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

Required SOW Language for Security Section

This project requires an OPSEC Plan and a Security Plan.

The contractor shall develop a comprehensive security program that provides overall protection of personnel, information, data, and facilities associated with fulfilling the Government requirement. This plan shall establish security practices and procedures that demonstrate how the contractor will meet and adhere to the security requirements outlined below prior to the commencement of product manufacturing, and shall be delivered to the Government within 30 calendar days of award. The contractor shall also ensure all subcontractors, consultants, researchers, etc. performing work on behalf of this effort, comply with all Operation Warp Speed and Project Agreement security requirements and prime contractor security plans.

- a) The Government will review in detail and submit comments within ten (10) business days to the Contracting Officer (CO) to be forwarded to the Contractor. The Contractor shall review the Draft Security Plan comments, and, submit a Final Security Plan to the U.S. Government within thirty (10) calendar days after receipt of the comments.
- b) The Security Plan shall include a timeline for compliance of all the required security measures outlined by the Government.
- c) Upon completion of initiating all security measures, the Contractor shall supply to the Contracting Officer a letter certifying compliance to the elements outlined in the Final Security Plan.

At a minimum, the Final Security Plan shall address the following items:

Security Requirements:

1. Facility Security Plan

Description: As part of the partner facility's overall security program, the contractor shall submit a written security plan with their proposal to the Agreement Officer for review and approval by Operation Warp Speed security subject matter experts. The performance of work under the Project Agreement will be in accordance with the approved security plan. The security plan will include the following processes and procedures at a minimum:

Security Administration	• organization chart and responsibilities • written security risk assessment for site • threat levels with identification matrix (High, Medium, or Low) • enhanced security procedures during elevated threats • liaison procedures with law enforcement • annual employee security education and training program
Personnel Security	• policies and procedures • candidate recruitment process • background investigations process • employment suitability policy • employee access determination • rules of behavior/ conduct • termination procedures • non-disclosure agreements
Physical Security Policies and Procedures	• internal/external access control • protective services • identification/badging • employee and visitor access controls • parking areas and access control • perimeter fencing/barriers • product shipping, receiving and transport security procedures • facility security lighting • restricted areas • signage • intrusion detection systems • alarm monitoring/response • closed circuit television • product storage security • other control measures as identified
Information Security	• identification and marking of sensitive information • access control • storage of information • document control procedures • retention/ destruction requirements
Information Technology/Cyber Security Policies and Procedures	• intrusion detection and prevention systems • threat identification • employee training (initial and annual) • encryption systems • identification of sensitive information/media • password policy (max days 90) • lock screen time out policy (minimum time 20 minutes) • removable media policy • laptop policy • removal of IT assets for domestic/foreign travel • access control and determination • VPN procedures • WiFi and Bluetooth disabled when not in use

	• system document control • system backup • system disaster recovery • incident response • system audit procedures • property accountability
2. Site Security Master Plan Description: The partner facility shall provide a site schematic for security systems which includes: main access points; security cameras; electronic access points; IT Server Room; Product Storage Freezer/Room; and bio-containment laboratories.	
3. Site Threat / Vulnerability / Risk Assessment Description: The partner facility shall provide a written risk assessment for the facility addressing: criminal threat, including crime data; foreign/domestic terrorist threat; industrial espionage; insider threats; natural disasters; and potential loss of critical infrastructure (power/water/natural gas, etc.) This assessment shall include recent data obtained from local law enforcement agencies. The assessment should be updated annually.	
4. Physical Security Description:	
Closed Circuit Television (CCTV) Monitoring	a) Layered (internal/external) CCTV coverage with time-lapse video recording for buildings and areas where critical assets are processed or stored. b) CCTV coverage must include entry and exits to critical facilities, perimeters, and areas within the facility deemed critical to the execution of the contract. c) Video recordings must be maintained for a minimum of 30 days. d) CCTV surveillance system must be on emergency power backup. e) CCTV coverage must include entry and exits to critical facilities, perimeters, and areas within the facility deemed critical to the execution of the contract. f) Video recordings must be maintained for a minimum of 30 days. g) CCTV surveillance system must be on emergency power backup.
Facility Lighting	a) Lighting must cover facility perimeter, parking areas, critical infrastructure, and entrances and exits to buildings. b) Lighting must have emergency power backup. c) Lighting must be sufficient for the effective operation of the CCTV surveillance system during hours of darkness.
Shipping and Receiving	a) Must have CCTV coverage and an electronic access control system. b) Must have procedures in place to control access and movement of drivers picking up or delivering shipments. c) Must identify drivers picking up Government products by government issued photo identification.
Access Control	a) Must have an electronic intrusion detection system with centralized monitoring. b) Responses to alarms must be immediate and documented in writing. c) Employ an electronic system (i.e., card key) to control access to areas where assets critical to the contract are located (facilities, laboratories, clean rooms, production facilities, warehouses, server rooms, records storage, etc.). d) The electronic access control should signal an alarm notification of unauthorized attempts to access restricted areas. e) Must have a system that provides a historical log of all key access transactions and kept on record for a minimum of 12 months.

	f) Must have procedures in place to track issuance of access cards to employees and the ability to deactivate cards when they are lost or an employee leaves the company. g) Response to electronic access control alarms must be immediate and documented in writing and kept on record for a minimum of 12 months. h) Should have written procedures to prevent employee piggybacking access i) to critical infrastructure (generators, air handlers, fuel storage, etc.) should be controlled and limited to those with a legitimate need for access. j) Must have a written manual key accountability and inventory process. k) Physical access controls should present a layered approach to critical assets within the facility.
Employee/Visitor Identification	a) Should issue company photo identification to all employees. b) Photo identification should be displayed above the waist anytime the employee is on company property. c) Visitors should be sponsored by an employee and must present government issued photo identification to enter the property. d) Visitors should be logged in and out of the facility and should be escorted by an employee while on the premises at all times.
Security Fencing	Requirements for security fencing will be determined by the criticality of the program, review of the security plan, threat assessment, and onsite security assessment.
Protective Security Forces	Requirements for security officers will be determined by the criticality of the program, review of the security plan, threat assessment, and onsite security assessment.
Protective Security Forces Operations	a) Must have in-service training program. b) Must have Use of Force Continuum. c) Must have communication systems available (i.e., landline on post, cell phones, handheld radio, and desktop computer). d) Must have Standing Post Orders. e) Must wear distinct uniform identifying them as security officers.
5. Security Operations	
Description:	
Information Sharing	a) Establish formal liaison with law enforcement. b) Meet in person at a minimum annually. Document meeting notes and keep them on file for a, minimum of 12 months. POC information for LE Officer that attended the meeting must be documented. c) Implement procedures for receiving and disseminating threat information.
Training	a) Conduct new employee security awareness training. b) Conduct and maintain records of annual security awareness training.
Security Management	a) Designate a knowledgeable security professional to manage the security of the facility. b) Ensure subcontractor compliance with all Government security requirements.
6. Personnel Security	
Description:	
Records Checks	Verification of social security number, date of birth, citizenship, education credentials, five-year previous employment history, five-year previous residence history, FDA disbarment, sex offender registry, credit check based upon position within the company; motor vehicle records check as appropriate; and local/national criminal history search.
Hiring and Retention Standards	a) Detailed policies and procedures concerning hiring and retention of employees, employee conduct, and off boarding procedures.

	b) Off Boarding procedures should be accomplished within 24 hour of employee leaving the company. This includes termination of all network access.
7. Information Security	
Description:	
Physical Document Control	a) Applicable documents shall be identified and marked as procurement sensitive, proprietary, or with appropriate government markings. b) Sensitive, proprietary, and government documents should be maintained in a lockable filing cabinet/desk or other storage device and not be left unattended. c) Access to sensitive information should be restricted to those with a need to know.
Document Destruction	Documents must be destroyed using approved destruction measures (i.e, shredders/approved third party vendors / pulverizing / incinerating).
8. Information Technology & Cybersecurity	
Description:	
Identity Management	a) Physical devices and systems within the organization are inventoried and accounted for annually. b) Organizational cybersecurity policy is established and communicated. c) Asset vulnerabilities are identified and documented. d) Cyber threat intelligence is received from information sharing forums and sources. e) Threats, vulnerabilities, likelihoods, and impacts are used to determine risk. f) Identities and credentials are issued, managed, verified, revoked, and audited for authorized devices, users and processes. g) Users, devices, and other assets are authenticated (e.g., single-factor, multifactor) commensurate with the risk of the transaction (e.g., individuals' security and privacy risks and other organizational risks)
Access Control	a) Limit information system access to authorized users. b) Identify information system users, processes acting on behalf of users, or devices and authenticate identities before allowing access. c) Limit physical access to information systems, equipment, and server rooms with electronic access controls. d) Limit access to/ verify access to use of external information systems.
Training	a) Ensure that personnel are trained and are made aware of the security risks associated with their activities and of the applicable laws, policies, standards, regulations, or procedures related to information technology systems.
Audit and Accountability	a) Create, protect, and retain information system audit records to the extent needed to enable the monitoring, analysis, investigation, and reporting of unlawful, unauthorized, or inappropriate system activity. Records must be kept for minimum must be kept for 12 months. b) Ensure the actions of individual information system users can be uniquely traced to those users. c) Update malicious code mechanisms when new releases are available. d) Perform periodic scans of the information system and real time scans of files from external sources as files are downloaded, opened, or executed.
Configuration Management	a) Establish and enforce security configuration settings. b) Implement sub networks for publically accessible system components that are physically or logically separated from internal networks.

Contingency Planning	a) Establish, implement, and maintain plans for emergency response, backup operations, and post-disaster recovery for information systems to ensure the availability of critical information resources at all times.
Incident Response	a) Establish an operational incident handling capability for information systems that includes adequate preparation, detection, analysis, containment, and recovery of cybersecurity incidents. Exercise this capability annually.
Media and Information Protection	a) Protect information system media, both paper and digital. b) Limit access to information on information systems media to authorized users. c) Sanitize and destroy media no longer in use. d) Control the use of removable media through technology or policy.
Physical and Environmental Protection	a) Limit access to information systems, equipment, and the respective operating environments to authorized individuals. b) Intrusion detection and prevention system employed on IT networks. c) Protect the physical and support infrastructure for all information systems. d) Protect information systems against environmental hazards. e) Escort visitors and monitor visitor activity.
Network Protection	Employ intrusion prevention and detection technology with immediate analysis capabilities.
9. Transportation Security Description: Adequate security controls must be implemented to protect materials while in transit from theft, destruction, manipulation, or damage.	
Drivers	a) Drivers must be vetted in accordance with the Government Personnel Security Requirements. b) Drivers must be trained on specific security and emergency procedures. c) Drivers must be equipped with backup communications. d) Driver identity must be 100 percent confirmed before the pick-up of any Government product. e) Drivers must never leave Government products unattended, and two drivers may be required for longer transport routes or critical products during times of emergency. f) Truck pickup and deliveries must be logged and kept on record for a minimum of 12 months.
Transport Routes	a) Transport routes should be pre-planned and never deviated from except when approved or in the event of an emergency. b) Transport routes should be continuously evaluated based upon new threats, significant planned events, weather, and other situations that may delay or disrupt transport.
Product Security	a) Government products must be secured with tamper resistant seals during transport, and the transport trailer must be locked and sealed. Tamper resistant seals must be verified as "secure" after the product is placed in the transport vehicle. b) Government products should be continually monitored by GPS technology while in transport, and any deviations from planned routes should be investigated and documented. c) Contingency plans should be in place to keep the product secure during emergencies such as accidents and transport vehicle breakdowns.
10. Security Reporting Requirements Description: The partner facility shall notify the Agreement Officer within 24 hours of any activity or incident that is in violation of established security standards or indicates the loss or theft of government products. The facts and circumstances associated with these incidents will be documented in writing for government review.	
11. Security Audits	

Description: The partner facility agrees to formal security audits conducted at the discretion of the government. Security audits may include both prime and subcontractor.

AWARD/CONTRACT		1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)		RATING	PAGE OF PAGES 1 30		
2. CONTRACT (Proc. Inst. Ident.) NO. W911SR2030004		3. EFFECTIVE DATE 01 Jul 2020		4. REQUISITION/PURCHASE REQUEST/PROJECT NO. 0011506526-0001			
5. ISSUED BY US ARMY RDECOM CONTRACTING CMD APG, EDGEWOOD CONTRACTING DIVISION E4455 LEITZAN ROAD ABERRDEEN PROVING GROUND MD 21010-5401		CODE W911SR	6. ADMINISTERED BY (If other than Item 5) DCMA DALLAS - S4402A 800 NORTH PEARL STREET SUITE 1630 DALLAS TX 75201-2843		CODE S4402A		
7. NAME AND ADDRESS OF CONTRACTOR (No., street, city, county, state and zip code) RETRACTABLE TECHNOLOGIES, INC. 511 LOBO LN LITTLE ELM TX 75068-5266			8. DELIVERY [] FOB ORIGIN [X] OTHER (See below)				
			9. DISCOUNT FOR PROMPT PAYMENT Net 30 Days				
			10. SUBMIT INVOICES (4 copies unless otherwise specified) TO THE ADDRESS SHOWN IN:		ITEM		
CODE 1BFK3		FACILITY CODE					
11. SHIP TO/MARK FOR BIOMEDICAL ADVANCED RESEARCH DEVELOPMENT (b) (6) ROOM 23E07 O'NEILL HOUSE OFFICE BUILDING WASHINGTON DC 20515		CODE W66XNH	12. PAYMENT WILL BE MADE BY DFAS-COLUMBUS CENTER DFAS-COMVEST ENTITLEMENT OPERATIONS P.O. BOX 182361 COLUMBUS OH 43218-2361		CODE HQ0339		
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					(b) (4)		
16. TABLE OF CONTENTS							
(X)	SEC.	DESCRIPTION	PAGE(S)	(X)	SEC.	DESCRIPTION	PAGE(S)
PART I - THE SCHEDULE				PART II - CONTRACT CLAUSES			
X	A	SOLICITATION/ CONTRACT FORM	1	X	1	CONTRACT CLAUSES	15 - 30
X	B	SUPPLIES OR SERVICES AND PRICES/ COSTS	2	PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACH.			
	C	DESCRIPTION/ SPECS./ WORK STATEMENT		J	LIST OF ATTACHMENTS		
	D	PACKAGING AND MARKING		PART IV - REPRESENTATIONS AND INSTRUCTIONS			
X	E	INSPECTION AND ACCEPTANCE	3	K	REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS		
X	F	DELIVERIES OR PERFORMANCE	4 - 5	L	INSTRS. CONDS., AND NOTICES TO OFFERORS		
X	G	CONTRACT ADMINISTRATION DATA	6	M	EVALUATION FACTORS FOR AWARD		
X	H	SPECIAL CONTRACT REQUIREMENTS	7 - 14				
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 (comes 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 sheet. 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)				20A. NAME OF CONTRACTING OFFICER (b) (6) TEL: (b) (6) EMAIL: (b) (6)			
19B. NAME OF CONTRACTOR BY (b) (6)		19C. DATE SIGNED 7/1/2020		20B. UNITED STATES OF AMERICA (b) (6) BY (b) (6)		20C. DATE SIGNED 1 July 2020	

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STANDARD FORM 26 (REV. 5/2011)
MULTI-DOD-ARMY-20-2554, 20-2562-A-000184
REPRODUCED BY GSA, FPMR (41 CFR) 101-11.6

Section B - Supplies or Services and Prices

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0001	TECHNOLOGY INVESTMENT AGREEMENT COST		(b) (4)		(b) (4) NTE
	Technology Investment Agreement (TIA) for Expanding Domestic Production of Needles & Syringes IAW vendor project plan dated (b) (4)				
	FOB: Destination				
	PURCHASE REQUEST NUMBER: (b) (4)				
	PSC CD: (b) (4)				
	ACRN AA			ESTIMATED COST	(b) (4)
	CIN: (b) (4)				

Section E - Inspection and Acceptance

INSPECTION AND ACCEPTANCE TERMS

Supplies/services will be inspected/accepted at:

CLIN	INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
0001	Destination	Government	Destination	Government

Section F - Deliveries or Performance

F.1 Supply Chain Resiliency Plan

F.2 The contractor shall develop and submit at the time of agreement award, a comprehensive Supply Chain Resiliency Program that provides identification and reporting of critical components associated with the secure supply of drug substance, drug product, and work-in-process through to finished goods.

- a) A critical component is defined as any material that is essential to the product or the manufacturing process associated with that product. Included in the definition are consumables and disposables associated with manufacturing. NOT included in the definition are facility and capital equipment.

F.3 Consideration of critical components includes the evaluation and potential impact of raw materials, excipients, active ingredients, substances, pieces, parts, software, firmware, labeling, assembly, testing, analytical and environmental componentry, reagents, or utility materials which are used in the manufacturing of a drug, cell banks, seed stocks, devices and key processing components and equipment. A clear example of a critical component is one where a sole supplier is utilized.

F.4 The contractor shall identify key equipment suppliers, their locations, local resources, and the associated control processes at the time of award. This document shall address planning and scheduling for active pharmaceutical ingredients, upstream, downstream, component assembly, finished drug product and delivery events as necessary for the delivery of product.

- a) Communication for these requirements shall be updated as part of an annual review, or as necessary, as part of regular contractual communications.
- b) For upstream and downstream processing, both single-use and re-usable in-place processing equipment, and manufacturing disposables also shall be addressed. For finished goods, the inspection, labeling, packaging, and associated machinery shall be addressed taking into account capacity capabilities.
- c) The focus on the aspects of resiliency shall be on critical components and aspects of complying with the contractual delivery schedule. Delivery methods shall be addressed, inclusive of items that are foreign-sourced, both high and low volume, which would significantly affect throughput and adherence to the contractually agreed deliveries.

F.5 The contractor shall articulate in the plan, the methodology for inventory control, production planning, scheduling processes and ordering mechanisms, as part of those agreed deliveries.

- a) Production rates and lead times shall be understood and communicated to the HHS/ASPR/BARDA Agreements Officer (AO) or the Agreements Officer's Representative (AOR) as necessary.
- b) Production throughput critical constraints should be well understood by activity and by design, and communicated to contractual personnel. As necessary, communication should focus on identification, exploitation, elevation, and secondary constraints of throughput, as appropriate.

F.6 Reports for critical items should include the following information:

- a) Critical Material
- b) Vendor
- c) Supplier, Manufacturing / Distribution Location
- d) Supplier Lead Time
- e) Shelf Life
- f) Transportation / Shipping restrictions

F.7 The AO and AOR reserve the right to request un-redacted copies of technical documents, during the period of performance, for distribution within the Government. Documents shall be provided within ten (10) days after AO issues the request. The Contractor may arrange for additional time if deemed necessary, and agreed to by the AO.

DELIVERY INFORMATION

CLIN	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
0001	POP 01-JUL-2020 TO 30-JUN-2030	(b) (4)	(b) (6)	W56XNH

FOB: Destination

Section G - Contract Administration Data

ACCOUNTING AND APPROPRIATION DATA

AA: (b) (4)
COST CODE: (b) (4)
AMOUNT: (b) (4)

ACRN	CLIN/SLIN	CIN	AMOUNT
AA	0001	(b) (4)	(b) (4)

Section H - Special Contract Requirements

H.1 Key Personnel

H.1.1 Pursuant to HHSAR 352.237-75 (Dec 2015), 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 Contractor voluntarily diverting any of the specified individuals to other programs or agreements the Contractor 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 agreement (including, when applicable, Human Subjects Testing requirements). If the employee of the Contractor is terminated for cause or separates from the Contractor voluntarily with less than thirty (30) calendar-day notice, the Contractor shall provide the maximum notice practicable under the circumstances. The Contractor shall not divert, replace, or announce any such change to key personnel without the written consent of the Agreements Officer. The agreement will be modified to add or delete key personnel as necessary to reflect the agreement of the parties. The following individuals are determined to be key personnel:

H.1.2 Substitution of Key Personnel

H.1.2.1 The Contractor 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.

H.1.2.2 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 Agreements 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 Agreements Officer or authorized representative will evaluate such requests and promptly notify the contractor of his approval or disapproval thereof.

H.1.2.3 The contractor further agrees to include the substance of this clause in any subcontract, which may be awarded under this agreement.

H.2 Disclosure of Information:

H.2.1 Performance under this agreement may require the Contractor to access non-public data and information proprietary to a Government agency, another Government Contractor 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 Contractor, nor Contractor 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 CO. The Contractor 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.

H.2.2 Consistent with HHS Directive 1139, the Contractor shall comply with HHS requirements for protection of non-public information. Unauthorized disclosure of nonpublic information is prohibited by the HHS's rules. Unauthorized disclosure may result in termination of the agreement, replacement of a Contractor employee, or other appropriate redress. Neither the Contractor nor the Contractor'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.

H.2.3 No information related to data obtained under this agreement shall be released or publicized without the prior written consent of the COR, 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 Contractor'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.

H.3 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 Contractor may, by mutual consent, identify elsewhere in this agreement 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 Agreements Officer and the Contractor 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 agreement that information to be utilized under this agreement, 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 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 Contractor shall obtain a written determination from the Agreements Officer prior to any release, disclosure, dissemination, or publication.
- f. Agreements 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.

H.4 Organizational Conflicts of Interest:

H.4.1 Performance under this agreement 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 agreement, 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 agreement, upon determination that an OCI has occurred.

H.4.2 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 Contractor's performance of this agreement, 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.

H.4.3 The Contractor shall notify the Agreements 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 Agreements Officer to either avoid or mitigate any such OCI. The Agreements Officer will have sole

discretion in accepting the Contractor's mitigation plan. In the event the Agreements 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 agreement requirements related to OCI.

H.4.4 Whenever performance of this agreement provides access to another Contractor's proprietary information, the Contractor shall:

(1) 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 CO within fifteen (15) calendar days of execution.

H.5 Operations Security (OPSEC)

H.5.1 The contractor shall develop and submit an OPSEC Standing Operating Procedure (SOP)/Plan within 30 calendar days of agreement award, to be reviewed and approved by the Government OPSEC lead for this effort. The final OPSEC plan, must address the Government's identified Critical Information List (CIL)

- a) All contractors supporting this effort must complete OPSEC Computer Based Training (CBT) that can be accessed via the (Insert applicable website here).

H.6 Security

H.6.1 The contractor shall develop a comprehensive security program that provides overall protection of personnel, information, data, and facilities associated with fulfilling the BARDA requirement. This plan shall establish security practices and procedures that demonstrate how the contractor will meet and adhere to the security requirements outlined below prior to the commencement of product manufacturing, and shall be delivered to the Government within 30 days of award. The contractor shall also ensure all subcontractors, consultants, researchers, etc. performing work on behalf of this effort, comply with all BARDA security requirements and prime contractor security plans.

- a) ASPR will review in detail and submit comments within ten (10) business days to the Agreements Officer (CO) to be forwarded to the Contractor. The Contractor shall review the Draft Security Plan comments, and, submit a Final Security Plan to the U.S. Government within thirty (10) calendar days after receipt of the comments.
- b) The Security Plan shall include a timeline for compliance of all the required security measures outlined by BARDA.
- c) Upon completion of initiating all security measures, the Contractor shall supply to the Agreements Officer a letter certifying compliance to the elements outlined in the Final Security Plan.

H.6.2 At a minimum, the Final Security Plan shall address the following items:

BARDA SECURITY REQUIREMENTS

1. Facility Security Plan	
Description: As part of the partner facility's overall security program, the contractor shall submit a written security plan with their proposal to BARDA for review and approval by BARDA security subject matter experts. The performance of work under the BARDA agreement will be in accordance with the approved security plan. The security plan will include the following processes and procedures at a minimum:	
Security Administration	• organization chart and responsibilities • written security risk assessment for site • threat levels with identification matrix (High, Medium, or Low) • enhanced security procedures during elevated threats • liaison procedures with law enforcement • annual employee security education and training program

Personnel Security	• policies and procedures • candidate recruitment process • background investigations process • employment suitability policy • employee access determination • rules of behavior/ conduct • termination procedures • non-disclosure agreements
Physical Security Policies and Procedures	• internal/external access control • protective services • identification/badging • employee and visitor access controls • parking areas and access control • perimeter fencing/barriers • product shipping, receiving and transport security procedures • facility security lighting • restricted areas • signage • intrusion detection systems • alarm monitoring/response • closed circuit television • product storage security • other control measures as identified
Information Security	• identification and marking of sensitive information • access control • storage of information • document control procedures • retention/ destruction requirements
Information Technology/Cyber Security Policies and Procedures	• intrusion detection and prevention systems • threat identification • employee training (initial and annual) • encryption systems • identification of sensitive information/media • password policy (max days 90) • lock screen time out policy (minimum time 20 minutes) • removable media policy • laptop policy • removal of IT assets for domestic/foreign travel • access control and determination • VPN procedures • WiFi and Bluetooth disabled when not in use • system document control • system backup • system disaster recovery • incident response • system audit procedures • property accountability
2. Site Security Master Plan Description: The partner facility shall provide a site schematic for security systems which includes: main access points; security cameras; electronic access points; IT Server Room; Product Storage Freezer/Room; and bio-containment laboratories.	
3. Site Threat / Vulnerability / Risk Assessment	

Description: The partner facility shall provide a written risk assessment for the facility addressing: criminal threat, including crime data; foreign/domestic terrorist threat; industrial espionage; insider threats; natural disasters; and potential loss of critical infrastructure (power/water/natural gas, etc.) This assessment shall include recent data obtained from local law enforcement agencies. The assessment should be updated annually.	
4. Physical Security	
Description:	
Closed Circuit Television (CCTV) Monitoring	a) Layered (internal/external) CCTV coverage with time-lapse video recording for buildings and areas where critical assets are processed or stored. b) CCTV coverage must include entry and exits to critical facilities, perimeters, and areas within the facility deemed critical to the execution of the agreement. c) Video recordings must be maintained for a minimum of 30 days. d) CCTV surveillance system must be on emergency power backup. e) CCTV coverage must include entry and exits to critical facilities, perimeters, and areas within the facility deemed critical to the execution of the agreement. f) Video recordings must be maintained for a minimum of 30 days. g) CCTV surveillance system must be on emergency power backup.
Facility Lighting	a) Lighting must cover facility perimeter, parking areas, critical infrastructure, and entrances and exits to buildings. b) Lighting must have emergency power backup. c) Lighting must be sufficient for the effective operation of the CCTV surveillance system during hours of darkness.
Shipping and Receiving	a) Must have CCTV coverage and an electronic access control system. b) Must have procedures in place to control access and movement of drivers picking up or delivering shipments. c) Must identify drivers picking up BARDA products by government issued photo identification.
Access Control	a) Must have an electronic intrusion detection system with centralized monitoring. b) Responses to alarms must be immediate and documented in writing. c) Employ an electronic system (i.e., card key) to control access to areas where assets critical to the agreement are located (facilities, laboratories, clean rooms, production facilities, warehouses, server rooms, records storage, etc.). d) The electronic access control should signal an alarm notification of unauthorized attempts to access restricted areas. e) Must have a system that provides a historical log of all key access transactions and kept on record for a minimum of 12 months. f) Must have procedures in place to track issuance of access cards to employees and the ability to deactivate cards when they are lost or an employee leaves the company. g) Response to electronic access control alarms must be immediate and documented in writing and kept on record for a minimum of 12 months. h) Should have written procedures to prevent employee piggybacking access i) to critical infrastructure (generators, air handlers, fuel storage, etc.) should be controlled and limited to those with a legitimate need for access. j) Must have a written manual key accountability and inventory process. k) Physical access controls should present a layered approach to critical assets within the facility.

Employee/Visitor Identification	a) Should issue company photo identification to all employees. b) Photo identification should be displayed above the waist anytime the employee is on company property. c) Visitors should be sponsored by an employee and must present government issued photo identification to enter the property. d) Visitors should be logged in and out of the facility and should be escorted by an employee while on the premises at all times.
Security Fencing	Requirements for security fencing will be determined by the criticality of the program, review of the security plan, threat assessment, and onsite security assessment.
Protective Security Forces	Requirements for security officers will be determined by the criticality of the program, review of the security plan, threat assessment, and onsite security assessment.
Protective Security Forces Operations	a) Must have in-service training program. b) Must have Use of Force Continuum. c) Must have communication systems available (i.e., landline on post, cell phones, handheld radio, and desktop computer). d) Must have Standing Post Orders. e) Must wear distinct uniform identifying them as security officers.
5. Security Operations	
Description:	
Information Sharing	a) Establish formal liaison with law enforcement. b) Meet in person at a minimum annually. Document meeting notes and keep them on file for a, minimum of 12 months. POC information for LE Officer that attended the meeting must be documented. c) Implement procedures for receiving and disseminating threat information.
Training	a) Conduct new employee security awareness training. b) Conduct and maintain records of annual security awareness training.
Security Management	a) Designate a knowledgeable security professional to manage the security of the facility. b) Ensure subcontractor compliance with all BARDA security requirements.
6. Personnel Security	
Description:	
Records Checks	Verification of social security number, date of birth, citizenship, education credentials, five-year previous employment history, five-year previous residence history, FDA disbarment, sex offender registry, credit check based upon position within the company; motor vehicle records check as appropriate; and local/national criminal history search.
Hiring and Retention Standards	a) Detailed policies and procedures concerning hiring and retention of employees, employee conduct, and off boarding procedures. b) Off Boarding procedures should be accomplished within 24 hour of employee leaving the company. This includes termination of all network access.
7. Information Security	
Description:	
Physical Document Control	a) Applicable documents shall be identified and marked as procurement sensitive, proprietary, or with appropriate government markings. b) Sensitive, proprietary, and government documents should be maintained in a lockable filing cabinet/desk or other storage device and not be left unattended. c) Access to sensitive information should be restricted to those with a need to know.

Document Destruction	Documents must be destroyed using approved destruction measures (i.e., shredders/approved third party vendors / pulverizing / incinerating).
8. Information Technology & Cybersecurity	
Description:	
Identity Management	a) Physical devices and systems within the organization are inventoried and accounted for annually. b) Organizational cybersecurity policy is established and communicated. c) Asset vulnerabilities are identified and documented. d) Cyber threat intelligence is received from information sharing forums and sources. e) Threats, vulnerabilities, likelihoods, and impacts are used to determine risk. f) Identities and credentials are issued, managed, verified, revoked, and audited for authorized devices, users and processes. g) Users, devices, and other assets are authenticated (e.g., single-factor, multifactor) commensurate with the risk of the transaction (e.g., individuals' security and privacy risks and other organizational risks)
Access Control	a) Limit information system access to authorized users. b) Identify information system users, processes acting on behalf of users, or devices and authenticate identities before allowing access. c) Limit physical access to information systems, equipment, and server rooms with electronic access controls. d) Limit access to/ verify access to use of external information systems.
Training	a) Ensure that personnel are trained and are made aware of the security risks associated with their activities and of the applicable laws, policies, standards, regulations, or procedures related to information technology systems.
Audit and Accountability	a) Create, protect, and retain information system audit records to the extent needed to enable the monitoring, analysis, investigation, and reporting of un-lawful, unauthorized, or inappropriate system activity. Records must be kept for minimum must be kept for 12 months. b) Ensure the actions of individual information system users can be uniquely traced to those users. c) Update malicious code mechanisms when new releases are available. d) Perform periodic scans of the information system and real time scans of files from external sources as files are downloaded, opened, or executed.
Configuration Management	a) Establish and enforce security configuration settings. b) Implement sub networks for publically accessible system components that are physically or logically separated from internal networks.
Contingency Planning	a) Establish, implement, and maintain plans for emergency response, backup operations, and post-disaster recovery for information systems to ensure the availability of critical information resources at all times.
Incident Response	a) Establish an operational incident handling capability for information systems that includes adequate preparation, detection, analysis, containment, and recovery of cybersecurity incidents. Exercise this capability annually.
Media and Information Protection	a) Protect information system media, both paper and digital. b) Limit access to information on information systems media to authorized users. c) Sanitize and destroy media no longer in use. d) Control the use of removable media through technology or policy.
Physical and Environmental Protection	a) Limit access to information systems, equipment, and the respective operating environments to authorized individuals.

	b) Intrusion detection and prevention system employed on IT networks. c) Protect the physical and support infrastructure for all information systems. d) Protect information systems against environmental hazards. e) Escort visitors and monitor visitor activity.
Network Protection	Employ intrusion prevention and detection technology with immediate analysis capabilities.
9. Transportation Security Description: Adequate security controls must be implemented to protect materials while in transit from theft, destruction, manipulation, or damage.	
Drivers	a) Drivers must be vetted in accordance with BARDA Personnel Security Requirements. b) Drivers must be trained on specific security and emergency procedures. c) Drivers must be equipped with backup communications. d) Driver identity must be 100 percent confirmed before the pick-up of any BARDA product. e) Drivers must never leave BARDA products unattended, and two drivers may be required for longer transport routes or critical products during times of emergency. f) Truck pickup and deliveries must be logged and kept on record for a minimum of 12 months.
Transport Routes	a) Transport routes should be pre-planned and never deviated from except when approved or in the event of an emergency. b) Transport routes should be continuously evaluated based upon new threats, significant planned events, weather, and other situations that may delay or disrupt transport.
Product Security	a) BARDA products must be secured with tamper resistant seals during transport, and the transport trailer must be locked and sealed. • Tamper resistant seals must be verified as “secure” after the product is placed in the transport vehicle. b) BARDA products should be continually monitored by GPS technology while in transport, and any deviations from planned routes should be investigated and documented. c) Contingency plans should be in place to keep the product secure during emergencies such as accidents and transport vehicle breakdowns.
10. Security Reporting Requirements Description: The partner facility shall notify the BARDA Security Team within 24 hours of any activity or incident that is in violation of established security standards or indicates the loss or theft of government products. The facts and circumstances associated with these incidents will be documented in writing for government review.	
11. Security Audits Description: The partner facility agrees to formal security audits conducted at the discretion of the government. Security audits may include both prime and subcontractor.	

Section I - Contract Clauses

TERMS & CONDITIONS

TECHNOLOGY INVESTMENT AGREEMENT

between

Retractable Technologies, Inc. (RTI)

and

**Department of Defense,
U.S. Army Contracting Command –Aberdeen Proving Ground,
Natick Contracting Division & Edgewood Contracting Division
(ACC-APG, NCD & ECD)**

on behalf of

Biomedical Advanced Research and Development Authority (BARDA)

for

Expanding Domestic Production of Needles & Syringes

Agreement No.:W911SR2030004

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

Total Cost Share for the Agreement: (b) (4)

Total Estimated Value of the Agreement: (b) (4)

Effective Date: 01 JUL 2020

TECHNOLOGY INVESTMENT AGREEMENT TERMS AND CONDITIONS

ARTICLES

1. Scope of Agreement
2. Term of Agreement
3. Order of Precedence
4. Program/Administrative Management
5. Financial Management & Payment
6. Accounting & Audit
7. Purchasing & Title
8. Cost Sharing
9. Government Preference
10. Records Retention & Government Access
11. Intellectual Property & Patent Rights
12. Data Rights
13. FDA Regulatory Requirements
14. Termination
15. Disputes
16. Reports & Distribution
17. Modification
18. Miscellaneous

(b) (4), (b) (3) (A)

RECITALS

This Agreement is entered into between the United States of America, Department of Defense, represented by ACC-APG, NCD & ECD ("Government") and Retractable Technologies, Inc. (RTI), ("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 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 MCS BAA Area of Interest is Mission Area 1, Medical Biological Prophylaxis.

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 research and other 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: Definitions at Subpart J of 32 CFR Part 37; National Policies at Appendix B, 32 CFR Part 22; Audits at Appendix C of 32 CFR Part 37. This TIA is subject good manufacturing practices (cGMPS) 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 as specifically referenced herein. If this instrument is awarded under the authority at 10 USC §2358, the Bayh-Dole Act, 35 U.S.C. §§ 200-212 applies, as applicable.

1.2 Principal Purpose

The Government and the Recipient agree that the principal purpose of this Agreement is for Government investment into the development/expansion of Recipient's manufacturing capacity for hypodermic safety needles and corresponding syringes in response to the worldwide Coronavirus (COVID-19) global pandemic (b) (4)

(b) (4)

(b) (4)

(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, for a period of 10 years, the "term" of the Agreement or "Period of Performance." *Period of performance* means the time during which a recipient or sub-recipient may incur new obligations to carry out the work authorized under an award or sub-award, respectively.

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, or any other Federal statutes directly affecting performance of this Agreement, including attachments where applicable; (b) Federal regulations specifically references; (c) the terms and conditions contained within the Agreement, including any documents incorporated; (d) programmatic requirements.

4. Program/Administrative Management

4.1 Program Management

The Recipient has full responsibility for the project/activity 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 as incorporated. The Recipient must consult the Program Office/Technical Representative through the Agreements Officer before deviating from the objectives or overall program of the research originally proposed. Non-compliance with any award provision of this clause may result in the withholding of funds and or the termination of the award.

4.2 Government Representatives: Agreements Officer (AO)

(b) (6)

Agreements Specialist (AS)

(b) (6)
ACC-APG, ECD

8456 Brigade Street
Building E4215

Aberdeen Proving Ground, MD 21010

(b) (6)

Administrative Grants Officer (AGO)
DCMA DALLAS – S4402A
4211 Cedar Springs Road
Dallas, TX 75219

(b) (6)

Biomedical Advanced Research and Development Authority (BARDA) Program Manager (PM)

(b) (6)

(b) (6)

4.3 Recipients Representatives

(b) (6)

5. Financial Management & Payment

5.1 Expenditure-Based.

This Agreement is an expenditure type 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.”

Payments shall be made on a monthly basis for expenditures incurred up to the agreed upon project ceiling & Government investment funding amount, for the duration of the Period of Performance.

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 AGO 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:

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 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 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: Invoice and Receiving Report (Combo)

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

(3) 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*

<i>Field Name in WAWF</i>	<i>Data to be entered in WA</i>
Pay Official DoDAAC	HQ0339
Issue By DoDAAC	W911SR
Admin DoDAAC	S4402A
Inspect By DoDAAC	W56XNH
Ship To Code	W56XNH

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

- RTI
- Cage Code: 1BFK3
- DUNS: 838024255

(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.

(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.

Administrative Grants Officer (AGO)
DCMA DALLAS – S4402A
4211 Cedar Springs Road
Dallas, TX 75219
214-670-9201

(b) (6)

(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).

6.2 Annual Audit Requirement.

The Recipient shall have an annual audit performed by the Defense Contract Audit Agency (DCAA), or, an independent auditor, in accordance with 32 CFR §37.650. It is preferable that DCAA conduct the audit if the Recipient will grant DCAA access to information and records required to complete the audit. The Recipient shall provide a copy of the auditor's report to the AO within 60-days after audit.

6.3 Program Income. 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). 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.

7. Purchasing & Title

7.1 Title to Property Acquired under Agreement. Title to real property, equipment, and supplies or intangible property that are acquired by the Recipient (whether by purchase, construction or fabrication, development, or otherwise) with Government funding vests in the Recipient conditionally as described at 32 CFR 37.685.

7.2 Disposition. Any Federal interest in the real property or equipment remaining after the term will be addressed at the time of property disposition. Disposition will be in accordance with 32 CFR 34.21.

7.3 Purchasing System. If the Recipient currently performs under DoD assistance instruments subject to the purchasing standards in 32 CFR 34.31, then that Part applies. Otherwise, the Recipient may use the existing purchasing systems, as long as applicable requirements are flowed down (37.705).

8. Cost Sharing

8.1 To the maximum extent practicable, the recipient must provide at least (b) (4) of the costs of the project, in accordance with § 37.215. *Total value* of the TIA means the total amount of costs that are currently expected to be charged to the award over its life, which includes amounts for the Federal share and any non-Federal cost sharing or matching required under the award; and any options, even if not yet exercised, for which the costs have been established in the award.

8.2 The Government funding is estimated to represent approximately (b) (4) of the overall amount necessary to accomplish the scope of work cited in the proposal (inclusive of all proposal revisions and appendices). The Recipient agrees to provide the resources in the manner shown in their proposal. Recipient's cost sharing contribution will occur within the term of the agreement but may not coincide with the Government's expenditure payments.

8.3 Failure of either Party to provide its respective total contribution may result in a unilateral modification to this Agreement by the AO to reflect proportional reduction in funding for the other Party.

9. Government Preference

(b) (4)



9.2 Precedence. Recipient agrees that upon Presidential Declaration of a Public Health Emergency, that Government orders will be provided precedence for completion on machines funded by the U.S. Government over and above any other orders. This requirements applies regardless of a DO or DX rating under the Defense Production Act.

9.3 Maintenance of equipment and availability of capacity. Recipient agrees that for a period of 10 years following the commissioning of equipment funded by this Agreement, that it shall maintain the equipment in such a way as to ensure that, should the rights established under 9.1 and 9.2 be in effect, there is capacity equal to that which was available at time of commissioning. Further, the Recipient agrees that should the equipment funded by this agreement be unavailable during a period in which the rights under 9.1 and 9.2 are in effect, the Recipient will make available to the Government equivalent capacity from equipment not funded under this agreement.

9.4. Inspection of equipment. The Recipient grants the Government the right to inspect at any time, upon provision of reasonable advance notice, the equipment funded by this agreement. This right shall be in effect for 10 years following commissioning of the equipment.

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. 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.

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 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 (2) 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 a non-exclusive 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 a nonexclusive, nontransferable, irrevocable, paid-up license for the Government to practice and have practiced the Invention.

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. Should any of these provisions be inconsistent with the Bayh-Dole Act, the statute takes precedence.

12. Data Rights:

12.1 All data generated in connection with the performance of the studies under this Agreement, or that arises out of the use of any materials or enabling technology provided or used by the Recipient in the performance of this Agreement, other materials or confidential information, whether conducted by the Government or the Recipient (collectively, the "Study Data"), shall be owned by the Recipient. The Government shall have the right to use, modify, reproduce, release, perform, display, or disclose data first produced in the performance of this Agreement within the Government and otherwise including use for Government procurement of the items covered by the data. The Government may, under a separate agreement or by modification to this agreement, obtain any rights to use or disclose the material or data to the extent that such material or data was produced outside the scope

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

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 the Awardee or the Government may have in data delivered under this Agreement, whether arising under this Agreement or otherwise, will not be affected by Awardee's failure to mark data pursuant to this Article. Any distribution markings shall be established by the GPM and incorporated prior to distribution.

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 "Unlimited Rights" (as that term is defined in DFARS 252.227-7014) held by the Government. 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.

12.4 Any 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.

13. U.S Food and Drug Administration (FDA) Regulatory Compliance

13.1 Good Manufacturing Practices (GMP) Compliance. To the extent required under the Federal Food, Drug, and Cosmetic Act, 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 FDA pertinent to the manufacturing capability established under this Agreement.

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.

14. Termination

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

15. 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 AO. The AO will review the matter and render a decision in writing. Any such decision is final and binding. In the event of a decision, within 60-calendar days of the referral for review (or such other period as agreed upon by the parties), either party may pursue any right or remedy provided by law in a court of competent jurisdiction as authorized by 28 U.S.C. 1491. Alternately, the parties may agree to explore and establish an Alternate Disputes Resolution procedure to resolve this dispute.

16. Reports & Distribution

16.1 Monthly Progress Reports. Submitted monthly no later than the 10th of the month. Recipient format acceptable. Electronic submission acceptable in MS Office or PDF format. Financial information shall be MS Excel format. Monthly reports shall NOT be marked proprietary and shall have Distribution Statement C (U.S. Government and their contractors). Each monthly report shall, at a minimum, contain the following:

- a. Summary of monthly progress for the Recipient's facilities/capabilities associated with this effort
- b. Summary of progress towards established milestones for each facility/capability
- c. Identification of any milestone that is slipping or missed, and discussion of path forward to bring milestone back to schedule, and impact on other milestones
- d. Summary of risks, discussion of potential impacts and efforts to mitigate
- e. Summary of overall schedule and changes from previous month
- f. Financial summary of Recipient costs incurred by month to date, vouchers submitted, and Government payments made

16.2 Quarterly-In-Process Reviews. Scheduled as needed, generally not more frequently than quarterly, at the Recipient's facilities. Duration: eight (8) hours max. Face-to-face review of previous quarter's activities. Informative in nature to keep BARDA apprised of project progress and to discuss issues that may require joint resolution, such as milestone changes, political impacts on objectives, schedule, funding.

16.3 Annual Financial Status Report. (37.880)

16.4 Final Report. Final Report shall not be marked proprietary, and shall have Distribution Statement C. Final report summarizing stated objectives and the progress that was achieved in meeting those objectives; summary of risks incurred, impacts and mitigation; quantitative discussion of needle & syringe production throughput improvements achieved; financial summary of project; schedule summary for project, comparing original schedule to final schedule; recommendations for path forward as applicable.

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 AO be effective or binding upon the Government. All such actions must be formalized by a proper contractual document executed by the AO. The only method by which this Agreement can be modified is by a formal, written modification signed by the AO. 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 PM with a copy to the AO. 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 AO is responsible for the review and verification of any recommendations.

17.3 Unilateral or Minor. The AO 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 proposal, proposal revision, proposal appendices, and collaboration plan(s), constitutes the entire Agreement between the Parties concerning the subject matter hereof and supersedes any prior understandings or written or oral Agreement relative to said matter. 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.

18.4 Liability. No Party to this Agreement shall be liable to the other Party for any property consumed, damaged, or destroyed in the performance of this Agreement, unless it is due to the negligence or willful misconduct of the Party or an employee or agent of the Party. In no event shall either Party be liable for special, incidental, or consequential damages arising from or connected with this Agreement.

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.

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

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

SIGNATURES:

Recipient

Government

(b) (6)

Signature
(b) (6)

Printed Name
(b) (6)

Title
7/1/2020

Date

(b) (6)

Signature
(b) (6)

Printed Name
Agreements Officer

Title

Date