

AWARD/CONTRACT		1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)			RATING	PAGE OF PAGES 1 26	
2. CONTRACT (Proc. Inst. Ident.) NO. W911NF2030003		3. EFFECTIVE DATE 05 Jun 2020		4. REQUISITION/PURCHASE REQUEST/PROJECT NO. 0011506457			
5. ISSUED BY US ARMY ACC-APG-RTP W911NF 800 PARK OFFICE DRIVE SUITE 4229 RESEARCH TRIANGLE PARK NC 27709		CODE W911NF	6. ADMINISTERED BY (If other than Item 5) DCMA HUNTSVILLE 1040 RESEARCH BLVD SUITE 100 MADISON AL 35758-2040		CODE S0107A	SCD: C	
7. NAME AND ADDRESS OF CONTRACTOR (No., street, city, county, state and zip code) SIO2 MEDICAL PRODUCTS, NC. 2250 R LEY ST AUBURN AL 36832-8070				8. DELIVERY [] FOB ORIGIN [X] OTHER (See below)			
				9. DISCOUNT FOR PROMPT PAYMENT			
CODE 8KP08		FACILITY CODE		10. SUBMIT INVOICES (4 copies unless otherwise specified) TO THE ADDRESS SHOWN IN:		ITEM	
11. SHIP TO/MARK FOR See Schedule		CODE	12. PAYMENT WILL BE MADE BY DFAS COLUMBUS CENTER DFAS-CO/SOUTH ENTITLEMENT OPERATIONS PO BOX 182264 COLUMBUS OH 43218-2264		CODE HQ0338		
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					\$143,000,000.00		
16. TABLE OF CONTENTS							
(X)	SEC.	DESCRIPTION	PAGE(S)	(X)	SEC.	DESCRIPTION	PAGE(S)
PART I - THE SCHEDULE				PART II - CONTRACT CLAUSES			
X	A	SOLICITATION/ CONTRACT FORM	1	I		CONTRACT CLAUSES	
X	B	SUPPLIES OR SERVICES AND PRICES/ COSTS	2 - 6	PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACH.			
X	C	DESCRIPTION/ SPECS./ WORK STATEMENT	7 - 23	J		LIST OF ATTACHMENTS	
	D	PACKAGING AND MARKING		PART IV - REPRESENTATIONS AND INSTRUCTIONS			
X	E	INSPECTION AND ACCEPTANCE	24	K		REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS	
X	F	DELIVERIES OR PERFORMANCE	25				
X	G	CONTRACT ADMINISTRATION DATA	26	L		INSTRS., CONDS., AND NOTICES TO OFFERORS	
	H	SPECIAL CONTRACT REQUIREMENTS		M		EVALUATION FACTORS FOR AWARD	
CONTRACTING OFFICER WILL COMPLETE ITEM 17 (SEALED-BID OR NEGOTIATED PROCUREMENT) OR 18 (SEALED-BID PROCUREMENT) AS APPLICABLE							
17 [X] CONTRACTOR'S NEGOTIATED AGREEMENT Contractor is required to sign this document and return 1 copies to issuing office. Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any continuation sheets for the consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the following documents: (a) this award/contract, (b) the solicitation, if any, and (c) such provisions, representations, certifications, and specifications, as are attached or incorporated by reference herein (Attachments are listed herein.)				18 [] SEALED-BID AWARD (Contractor is not required to sign this document) Your bid on Solicitation Number _____ including the additions or changes made by you which additions or changes are set forth in full above, is hereby accepted as to the terms listed above and on any continuation sheets. This award consummates the contract which consists of the following documents: (a) the Government's solicitation and your bid, and (b) this award/contract. No further contractual document is necessary. (Block 18 should be checked only when awarding a sealed-bid contract.)			
19A. NAME AND TITLE OF SIGNER (Type or print) (b) (6)				2 (b) (6) TEL: _____ EMAIL: _____			
19B. NAME OF CONTRACTOR (b) (6) BY _____ (Signature of person authorized to sign)		19C. DATE SIGNED 06/05/2020		20B. UNITED STATES OF AMERICA (b) (6) BY _____ (Signature of Contracting Officer)		20C. DATE SIGNED 5 Jun 2020	

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19A. NAME AND TITLE OF SIGNER (Type or print)				20A. NAME OF CONTRACTING OFFICER (b) (6)		
19B. NAME OF CONTRACTOR		19C. DATE SIGNED		20B. UNITED STATES OF AMERICA (b) (6)		20C. DATE SIGNED 05-Jun-2020
BY _____ (Signature of person authorized to sign)				BY _____ (Signature of Contracting Officer)		

Section B - Supplies or Services and Prices

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0001	VIAL INITIATIVEFFP SEE ATTACHMENT B - MILESTONE SCHEDULE AND BUDGET FOB: Destination PURCHASE REQUEST NUMBER: 0011506457 PSC CD: K065	1	Job	\$143,000,000.00	\$143,000,000.00
NET AMT					\$143,000,000.00
ACRN AA CIN: GFEBS001150645700010					\$143,000,000.00

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0002 OPTION	YEAR 2 CAPACITYFFP MFN Pricing for Government and MCM Partners This option is for most favored nation pricing for orders placed by Government contractors who are producing product to fulfill BARDA contracts and to extend the Government's priority access in the event of a declared public health FOB: Destination PSC CD: K065	1	Job		(b)
NET AMT					

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0003 OPTION	YEAR 3 CAPACITYFFP MFN Pricing for Government and MCM Partners This option is for most favored nation pricing for orders placed by Government contractors who are producing product to fulfill BARDA contracts and to extend the Government's priority access in the event of a declared public health FOB: Destination PSC CD: K065	1	Job		(b)

NET AMT

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0004 OPTION	YEAR 4 CAPACITYFFP MFN Pricing for Government and MCM Partners This option is for most favored nation pricing for orders placed by Government contractors who are producing product to fulfill BARDA contracts and to extend the Government's priority access in the event of a declared public health FOB: Destination PSC CD: K065	1	Job		(b)

NET AMT

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0005 OPTION	YEAR 5 CAPACITYFFP MFN Pricing for Government and MCM Partners This option is for most favored nation pricing for orders placed by Government contractors who are producing product to fulfill BARDA contracts and to extend the Government's priority access in the event of a declared public health FOB: Destination PSC CD: K065	1	Job		(b)

NET AMT

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0006 OPTION	YEAR 6 CAPACITYFFP MFN Pricing for Government and MCM Partners This option is for most favored nation pricing for orders placed by Government contractors who are producing product to fulfill BARDA contracts and to extend the Government's priority access in the event of a declared public health FOB: Destination PSC CD: K065	1	Job		(b)

NET AMT

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0007 OPTION	YEAR 7 CAPACITYFFP MFN Pricing for Government and MCM Partners This option is for most favored nation pricing for orders placed by Government contractors who are producing product to fulfill BARDA contracts and to extend the Government's priority access in the event of a declared public health FOB: Destination PSC CD: K065	1	Job		(b)

NET AMT

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0008 OPTION	YEAR 8 CAPACITYFFP MFN Pricing for Government and MCM Partners This option is for most favored nation pricing for orders placed by Government contractors who are producing product to fulfill BARDA contracts and to extend the Government's priority access in the event of a declared public health FOB: Destination PSC CD: K065	1	Job		(b)

NET AMT

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0009 OPTION	YEAR 9 CAPACITYFFP MFN Pricing for Government and MCM Partners This option is for most favored nation pricing for orders placed by Government contractors who are producing product to fulfill BARDA contracts and to extend the Government's priority access in the event of a declared public health FOB: Destination PSC CD: K065	1	Job		(b)

NET AMT

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0010 OPTION	YEAR 10 CAPACITYFFP MFN Pricing for Government and MCM Partners This option is for most favored nation pricing for orders placed by Government contractors who are producing product to fulfill BARDA contracts and to extend the Government's priority access in the event of a declared public health FOB: Destination PSC CD: K065	1	Job		(b)

NET AMT

Section C - Descriptions and Specifications

TECHNOLOGY INVESTMENT AGREEMENT

TECHNOLOGY INVESTMENT AGREEMENT BETWEEN

SIO2 MEDICAL PRODUCTS INC, Auburn AL

AND

***U.S. Army Contracting Command –Aberdeen Proving Ground,
Research Triangle Park Division
(ACC-APG-RTP)***

on behalf of the

Biomedical Advanced Research and Development Authority (BARDA)

CONCERNING

Developing a Domestic Continental U.S.-Based Hybrid Pharmaceutical Vial.

Agreement No.:W911NF-20-3-0003

Total Amount of Government Funding for the Agreement: \$143,000,000.00

Total Cost Share for the Agreement: \$128,438,496.00

Total Estimated Value of the Agreement: \$271,438,496.00

Period of Performance: 36 Months

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

CFDA Number: 12.360

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

ATTACHMENTS

- A. Recipient's Proposal
- B. Milestone Schedule and Budget
- C. Collaboration Plan

RECITALS

This Agreement is entered into between the United States of America, Department of Defense, represented by ACC-APG-RTP (“Government”) and SIO2 Medical Products Inc (“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 MSC 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, to the extent applicable: 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 to good manufacturing practices (eGMPS) at 21 CFR 210 and 211, as applicable. The Federal Acquisition Regulation (FAR), Defense Federal Acquisition Regulation Supplement (DFARS), DoD Grant and Agreement Regulations (DoDGARs), or other regulatory and statutory requirements apply only as specifically referenced herein. If this instrument is awarded under 10 USC §2358, then the Bayh-Dole Act, 35 U.S.C. §200-212 also applies, if applicable.

1.2 Principal Purpose

The Government and the Recipient agree that the principal purpose of this Agreement is for Government investment into the expansion of Recipient’s existing capacities to support research efforts in pursuit of domestic development and distribution of a vaccine in response to the worldwide COVID-19 pandemic. SIO2 Medical Products Inc.’s proposal titled “Developing a Domestic Continental U.S.-Based Hybrid Pharmaceutical Vial,” dated 26 May 2020, including all revisions and appendices, is fully incorporated (the “Proposal” or “Project”). 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 36 months, the “term” of the Agreement or “Period of Performance.” *Period of performance* means the time during which a recipient or subrecipient may incur new obligations to carry out the work authorized under an award or subaward, respectively.

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

4.2 Government Representatives:

Agreements Officer

(b) (6)

Administrative Agreements Officer

(b) (6)

(b) (6)

5. Financial Management & Payment

5.1 Fixed Support.

This Agreement is a fixed-support type Technology Investment Agreement (TIA) as described in 32 CFR §37.300. Fixed-support means that the amount of assistance established at the time of award is not meant to be adjusted later if the research project is carried out to completion. Payments will be based on Payable Milestones as defined in 32 CFR 37.815. These are payments made according to a schedule that is based on predetermined measures of technical progress or other payable milestones. This approach relies upon the fact that, as research progresses throughout the term of the agreement, observable activity will be taking place. The Recipient is paid upon the accomplishment of the predetermined measure of progress. Post-award administrators may adjust amounts of future milestone payments if a project's expenditures fall too far below the projections that were the basis for setting the amounts (*see* §37.575(c) and §37.1105(c)).

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 of milestone acceptance via 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*

Note: Blacked out areas below appear on original contract

Pay Official DoDAAC	HQ0338
Issue By DoDAAC	W911NF
Admin DoDAAC	S0107A
Ship From Code	N/A
Mark For Code	N/A
Service Approver DoDAAC	S0107A
Accept at Other DoDAAC	N/A
LPO DoDAAC	N/A
DCAA Auditor DoDAAC	N/A
Other DoDAAC(s)	N/A

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

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

(g) WAWF point of contact.

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

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

6. Accounting & Audit

6.1. 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 (32 CFR § 34.21). 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) using Government funding vests in the Recipient. The Government authorizes the Recipient to purchase equipment or property with Government funding pursuant to 32 CFR 37.685(b)(2) (see also 32 CFR 34.21(a)); however it retains the Federal interest described in Section 9 in the property or equipment directly charged or contributed to the Project (the "Government Interest Property") until the end of the period of performance and the exercised optional availability periods. In light of the continuing nature of the Project, unless the Recipient and the Government otherwise mutually agree, the disposition of the Government Interest Property will not occur until the latter of (i) the Government Interest Property no longer being needed for Federally sponsored projects or (ii) ten (10) years after execution of the Agreement (i.e., the period during which the activities described in Section 1.2 are currently contemplated to occur). The Government and Recipient anticipate that at the time of disposition, the fair market value of the Government Interest Property will be nominal. Further, the Government is authorized to allow vesting without further obligation when a statute specifically authorizes it to do so, and the Government does hereby allow such vesting if and when such a statute is identified. For the avoidance of doubt and to the extent the use is consistent with the activities described in Section 1.2, no use charges will be payable pursuant to 32 CFR § 34.21(d)(iii).

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

8. Cost Sharing

8.1 *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. The Total Amount of Government Funding for the Agreement is \$143,000,000.00; the Total Cost Share for the Agreement is \$128,438,496.00, and; the Total Estimated Value of the Agreement is \$271,438,496.00

9. Government Preference

9.1 Pricing. During the period of performance and the exercised optional availability periods, the Recipient agrees that, in the event that it offers, sells or otherwise provides a Qualifying Product (as defined below) to any Qualifying Third Party (as defined below) at a per unit price lower than that offered for the same Qualifying Product to the Government or a third party purchasing Qualifying Product pursuant to a designation by the Government pursuant to Section 9.2 or 9.3 (an "MCM Partner"), 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 or an MCM Partner. For any purchases that were made after the lower price was first extended to the Qualifying Third Party, the Recipient shall reimburse the Government or the MCM Partner, as applicable, the difference between the lower price provided to the Qualifying Third Party and the price provided to the Government or such MCM Partner, as applicable, 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 or the MCM Partner. For the purposes of this Article, (a) the per unit purchase price paid for a Qualifying Product is the average net purchase price paid over a calendar year for the Qualifying Product after any discounts, rebates, prepayments by the customer, volume- or other-based adjustments or other adjustments or arrangements which effectively modify the price paid for the Qualifying Product, but excluding payments for taxes, duties, tariffs, freight, insurance, and other shipping or delivery related charges, (b) a "Qualifying Product" is a pharmaceutical glass packaging container manufactured, in whole or in part, utilizing Government Interest Property, and (c) a "Qualifying Third Party" is a third party who purchases a Qualifying Product for use in commercial production other than as a designee of the Government pursuant to Section 9.2 or 9.3.

9.2 Precedence. During the period of performance and the exercised optional availability periods and upon a Presidential Declaration of a Public Health Emergency (a "PHE"), Recipient shall grant the Government and third

parties designated by the Government the right to place Priority Orders (as defined below) for a quarterly quantity of Qualifying Product up to the Stated Capacity (as defined below), so long as the Qualifying Product are intended for use to address the PHE. The Agreements Officer shall provide written notice to Recipient of any such designated third parties. In the event that the Priority Orders exceed the Stated Capacity, Recipient shall notify the Government and allow the Government to prioritize the Priority Orders.

9.3 Continued Pricing. Subject to Section 9.2 and during the exercised optional availability periods, the Recipient agrees that the Government's designated third parties who are producing product to fulfill BARDA contracts shall have the right to place orders for applicable Qualifying Product at the pricing described in Section 9.1; provided, that the quantity of such Qualifying Product shall not exceed the Stated Capacity or the amount required to fulfill the designated third party's BARDA contract. The Recipient agrees to accept and fulfill such orders consistent with its standard practices. The Agreements Officer shall provide written notice to Recipient of any such designated third parties and the quantity of Qualifying Products that such designated third party is authorized to purchase.

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 months of being notified of the discovery of an invention or filing a patent application covering an Invention, each Party will provide notice of such discovery or filing to the other Party. The Parties will reasonably cooperate with each other in the preparation, filing, and prosecution of any patent application claiming an Invention. Any Party filing a patent application will bear expenses associated with filing and prosecuting the application, as well as maintaining any patents that issue from the application, unless otherwise agreed by the Parties.

11.5 Licenses. Upon the Recipient's request, the Government agrees to enter into good faith negotiations regarding the receipt of a nonexclusive commercialization license covering the Government's interest in any Invention made in whole or in part by a Government employee. Any Invention made by a Recipient employee is subject to 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. If there is any conflict between this section and the Bayh-Dole Act, the statute prevails.

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. FDA Regulatory Compliance

13.1 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 U.S. Food and Drug Administration (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.

13.3 Regulatory Filings. The Recipient shall file, maintain, and update one or more confidential Type III drug master files with the FDA necessary to the performance of this Agreement (collectively, "DMF"). Each DMF shall include the information necessary to support MCM Partner regulatory submissions. At the Government's request, Recipient shall provide relevant MCM Partners with a Letter of Authorization to use in referencing Recipient's DMF(s) as part of the MCM Partners' regulatory submissions to FDA.

14. Termination

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

15. Disputes

15.1 ADR. For any disagreement, claim, or dispute arising under this Agreement, the parties shall communicate with one another in good faith and in a timely and cooperative manner. Whenever disputes, disagreements, or misunderstandings arise, the parties shall attempt to resolve the issue by discussion and mutual agreement as soon as practicable. Failing resolution by mutual agreement, the aggrieved party shall request a resolution in writing from the AO. Alternately, the parties may agree to explore and establish an Alternate Disputes Resolution procedure to resolve this dispute.

15.2 Claims.

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

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

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

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

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

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

15.4 Formal Administrative Appeals

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

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

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

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

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

15.5 Non-exclusivity of remedies. Either party may pursue any right or remedy provided by law in a court of competent jurisdiction as authorized by 28 U.S.C. 1491.

16. Reports & Distribution

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: 8 hrs 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 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 vial 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 Agreement Officer be effective or binding upon the Government. All such actions must be formalized by a proper contractual document executed by the Agreement Officer. The only method by which this Agreement can be modified is by a formal, written modification signed by the Agreements Officer. No other communications, whether oral or in writing, shall modify this Agreement.

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

**ATTACHMENT A – RECIPIENT’S PROPOSAL
EXTERNAL ATTACHMENT**

(b) (4)

[Redacted text block]

[Redacted]	[Redacted]
[Redacted]	[Redacted]
[Redacted]	[Redacted]
[Redacted]	[Redacted]

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	N/A	N/A	N/A	Government
0002	N/A	N/A	N/A	Government
0003	N/A	N/A	N/A	Government
0004	N/A	N/A	N/A	Government
0005	N/A	N/A	N/A	Government
0006	N/A	N/A	N/A	Government
0007	N/A	N/A	N/A	Government
0008	N/A	N/A	N/A	Government
0009	N/A	N/A	N/A	Government
0010	N/A	N/A	N/A	Government

Section F - Deliveries or Performance

DELIVERY INFORMATION

CLIN	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
0001	POP 05-JUN-2020 TO 04-JUN-2021	N/A	JPM MEDICAL JPM MEDICAL 1564 FREEDMAN DRIVE FORT DETRICK, MD MD 21702 FOB: Destination	W56XNH
0002	POP 05-JUN-2021 TO 04-JUN-2022	N/A	N/A FOB: Destination	
0003	POP 05-JUN-2022 TO 04-JUN-2023	N/A	N/A FOB: Destination	
0004	POP 05-JUN-2023 TO 04-JUN-2024	N/A	N/A FOB: Destination	
0005	POP 05-JUN-2024 TO 04-JUN-2025	N/A	N/A FOB: Destination	
0006	POP 05-JUN-2025 TO 04-JUN-2026	N/A	N/A FOB: Destination	
0007	POP 05-JUN-2026 TO 04-JUN-2027	N/A	N/A FOB: Destination	
0008	POP 05-JUN-2027 TO 04-JUN-2028	N/A	N/A FOB: Destination	
0009	POP 05-JUN-2028 TO 04-JUN-2029	N/A	N/A FOB: Destination	
0010	POP 05-JUN-2029 TO 04-JUN-2030	N/A	N/A FOB: Destination	

Section G - Contract Administration Data

ACCOUNTING AND APPROPRIATION DATA

AA: 0212020202120400000664643255 S.0074658.5.1 6100.9000021001
COST CODE: A5XAH
AMOUNT: \$143,000,000.00

ACRN	CLIN/SLIN	CIN	AMOUNT
AA	0001	GFEB001150645700010	\$143,000,000.00

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT				1 CONTRACT ID CODE	PAGE OF PAGES	
				J	1 10	
2 AMENDMENT/MODIFICATION NO P00001	3 EFFECTIVE DATE 18-Jun-2020	4 REQUISITION/PURCHASE REQ NO 0011506457		5 PROJECT NO (If applicable)		
6 ISSUED BY US ARMY ACC-APG-RTP W911NF 800 PARK OFFICE DRIVE SUITE 4229 RESEARCH TRIANGLE PARK NC 27709	CODE W911NF	7 ADMINISTERED BY (If other than item 6) See Item 6		CODE SCD: C		
8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code) SIO2 MEDICAL PRODUCTS, NC. 2250 R LEY ST AUBURN AL 36832-8070				9A. AMENDMENT OF SOLICITATION NO.		
				9B. DATED (SEE ITEM 11)		
				X	10A. MOD. OF CONTRACT/ORDER NO. W911NF2030003	
				X	10B. DATED (SEE ITEM 13) 05-Jun-2020	
CODE 8KP08	FACILITY CODE					
11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS						
<input type="checkbox"/> The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of offer <input type="checkbox"/> is extended, <input type="checkbox"/> is not extended. 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)						
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.						
X	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).					
C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:						
D. OTHER (Specify type of modification and authority)						
E. IMPORTANT: Contractor <input checked="" type="checkbox"/> is not, <input type="checkbox"/> is required to sign this document and return _____ copies to the issuing office.						
14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.) Modification Control Number: (b) (6) COVID-19: The purpose of this modification is to make administrative changes to correct and clarify payment instructions.						
Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect						
15A. NAME AND TITLE OF SIGNER (Type or print)			16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)			
			(b) (6) / CONTRACTING OFFICER			
			TEL: (b) (6) EMAIL: (b) (6)			
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. BY		16C. DATE SIGNED		
(Signature of person authorized to sign)		(b) (6)		18-Jun-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:

MODIFICATION

This document constitutes **Modification P00001** to Technology Investment Agreement W911NF-20-3-0003, SIO2 Medical Products Inc.

The purpose of this modification is to: (1) change the address of the Administrative Office in Block 6 of the cover sheet of the Agreement to the Issuing Office Address and (2) Clarify the Financial Management and Payment Instructions in Article 5 of the Basic Agreement. Therefore, the following changes are hereby incorporated:

1. **Article 4, Program/Administrative Management, SubArticle 4.2 Government Representatives, REMOVE: Administrative Agreements Officer**
2. **Article 5, Financial Management and Payment shall be changed to read as follows:**

FROM

5. Financial Management & Payment

5.1 Fixed Support.

This Agreement is a fixed-support type Technology Investment Agreement (TIA) as described in 32 CFR §37.300. Fixed-support means that the amount of assistance established at the time of award is not meant to be adjusted later if the research project is carried out to completion. Payments will be based on Payable Milestones as defined in 32 CFR 37.815. These are payments made according to a schedule that is based on predetermined measures of technical progress or other payable milestones. This approach relies upon the fact that, as research progresses throughout the term of the agreement, observable activity will be taking place. The Recipient is paid upon the accomplishment of the predetermined measure of progress. Post-award administrators may adjust amounts of future milestone payments if a project's expenditures fall too far below the projections that were the basis for setting the amounts (*see* §37.575(c) and §37.1105(c)).

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 of milestone acceptance via 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*

Pay Official DoDAAC	HQ0338
Issue By DoDAAC	W911NF
Admin DoDAAC	S0107A
Ship From Code N/A	
Mark For Code N/A	
Service Approver DoDAAC	S0107A
Accept at Other DoDAAC	N/A
LPO DoDAAC	N/A
DCAA Auditor DoDAAC	N/A

Other DoDAAC(s)	N/A
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(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.

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

TO:

6. Financial Management & Payment

6.1 Fixed Support.

This Agreement is a fixed-support type Technology Investment Agreement (TIA) as described in 32 CFR §37.300. Fixed-support means that the amount of assistance established at the time of award is not meant to be adjusted later if the research project is carried out to completion. Payments will be based on Payable Milestones as defined in 32 CFR 37.815. These are payments made according to a schedule that is based on predetermined measures of technical progress or other payable milestones. This approach relies upon the fact that, as research progresses throughout the term of the agreement, observable activity will be taking place. The Recipient is paid upon the accomplishment of the predetermined measure of progress. Post-award administrators may adjust amounts of future milestone payments if a project's expenditures fall too far below the projections that were the basis for setting the amounts (*see* §37.575(c) and §37.1105(c)). Performance based payments will be made in accordance with FAR clause 52.232-32 which is cited in its entirety in this award.

6.2 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.

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

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

6.3.2. 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).

6.3.3. 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:

6.3.4. 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.
- (g) 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*

Pay Official DoDAAC	HQ0338
Issue By DoDAAC	W911NF
Admin DoDAAC	W911NF
Ship From Code N/A	
Mark For Code N/A	
Service Approver DoDAAC	W911NF
Accept at Other DoDAAC	N/A
LPO DoDAAC	N/A
DCAA Auditor DoDAAC	N/A
Other DoDAAC(s)	N/A

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

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

(6) If the vendor is re-submitting invoices they should ALWAYS change the invoice number with the resubmission: example SIO2001R (R for resubmission) (or, SIO2001R1, so that you can count the resubmissions SIO2001R2, Sio2001R3 if it gets to the 3rd resubmission.

(f) WAWF point of contact.

a. The Recipient may obtain clarification regarding invoicing in WAWF from the following contracting activity's WAWF point of contact.: Technical WAWF help, contact the WAWF helpdesk at 866-618-5988.

SECTION A - SOLICITATION/CONTRACT FORM

The 'administered by' organization has changed from

DCMA HUNTSVILLE
1040 RESEARCH BLVD
SUITE 100
MADISON AL 35758-2040

to

US ARMY ACC-APG-RTP W911NF
800 PARK OFFICE DRIVE
SUITE 4229
RESEARCH TRIANGLE PARK NC 27709

SECTION B - SUPPLIES OR SERVICES AND PRICES

Global Changes

CLIN 0001 -- CLIN 0010

The unit of issue has changed from Job to Lot.

The following have been added by full text:

52.232-32 PERFORMANCE-BASED PAYMENTS (APR 2012)

(a) Amount of payments and limitations on payments. Subject to such other limitations and conditions as are specified in this contract and this clause, the amount of payments and limitations on payments shall be specified in the contract's description of the basis for payment.

(b) Contractor request for performance-based payment. The Contractor may submit requests for payment of performance-based payments not more frequently than monthly, in a form and manner acceptable to the Contracting Officer. Unless otherwise authorized by the Contracting Officer, all performance-based payments in any period for which payment is being requested shall be included in a single request, appropriately itemized and totaled. The Contractor's request shall contain the information and certification detailed in paragraphs (l) and (m) of this clause.

(c) Approval and payment of requests.

(1) The Contractor shall not be entitled to payment of a request for performance-based payment prior to successful accomplishment of the event or performance criterion for which payment is requested. The Contracting Officer shall determine whether the event or performance criterion for which payment is requested has been successfully accomplished in accordance with the terms of the contract. The Contracting Officer may, at any time, require the Contractor to substantiate the successful performance of any event or performance criterion which has been or is represented as being payable.

(2) A payment under this performance-based payment clause is a contract financing payment under the Prompt Payment clause of this contract and not subject to the interest penalty provisions of the Prompt Payment Act. The designated payment office will pay approved requests on the **-15th day or as soon as possible**----- [Contracting Officer insert day as prescribed by agency head; if not prescribed, insert "30th"] day after receipt of the request for performance-based payment by the designated payment office. However, the designated payment office is not required to provide payment if the Contracting Officer requires substantiation as provided in paragraph (c)(1) of this clause, or inquiries into the status of an event or performance criterion, or into any of the conditions listed in paragraph (e) of this clause, or into the Contractor certification. The payment period will not begin until the Contracting Officer approves the request.

(3) The approval by the Contracting Officer of a request for performance-based payment does not constitute an acceptance by the Government and does not excuse the Contractor from performance of obligations under this contract.

(d) Liquidation of performance-based payments.

(1) Performance-based finance amounts paid prior to payment for delivery of an item shall be liquidated by deducting a percentage or a designated dollar amount from the delivery payment. If the performance-based finance payments are on a delivery item basis, the liquidation amount for each such line item shall be the percent of that delivery item price that was previously paid under performance-based finance payments or the designated dollar amount. If the performance-based finance payments are on a whole contract basis, liquidation shall be by either predesignated liquidation amounts or a liquidation percentage.

(2) If at any time the amount of payments under this contract exceeds any limitation in this contract, the Contractor shall repay to the Government the excess. Unless otherwise determined by the Contracting Officer, such excess shall be credited as a reduction in the unliquidated performance-based payment balance(s), after adjustment of invoice payments and balances for any retroactive price adjustments.

(e) Reduction or suspension of performance-based payments. The Contracting Officer may reduce or suspend performance-based payments, liquidate performance-based payments by deduction from any payment under the contract, or take a combination of these actions after finding upon substantial evidence any of the following conditions:

(1) The Contractor failed to comply with any material requirement of this contract (which includes paragraphs (h) and (i) of this clause).

(2) Performance of this contract is endangered by the Contractor's --

(i) Failure to make progress; or

(ii) Unsatisfactory financial condition.

(3) The Contractor is delinquent in payment of any subcontractor or supplier under this contract in the ordinary course of business.

(f) Title.

(1) Title to the property described in this paragraph (f) shall vest in the Government. Vestiture shall be immediately upon the date of the first performance-based payment under this contract, for property acquired or produced before that date. Otherwise, vestiture shall occur when the property is or should have been allocable or properly chargeable to this contract

(2) "Property," as used in this clause, includes all of the following described items acquired or produced by the Contractor that are or should be allocable or properly chargeable to this contract under sound and generally accepted accounting principles and practices:

(i) Parts, materials, inventories, and work in process;

(ii) Special tooling and special test equipment to which the Government is to acquire title;

(iii) Nondurable (i.e., noncapital) tools, jigs, dies, fixtures, molds, patterns, taps, gauges, test equipment and other similar manufacturing aids, title to which would not be obtained as special tooling under subparagraph (f)(2)(ii) of this clause; and

(iv) Drawings and technical data, to the extent the Contractor or subcontractors are required to deliver them to the Government by other clauses of this contract.

(3) Although title to property is in the Government under this clause, other applicable clauses of this contract (e.g., the termination or clauses) shall determine the handling and disposition of the property.

(4) The Contractor may sell any scrap resulting from production under this contract, without requesting the Contracting Officer's approval, provided that any significant reduction in the value of the property to which the Government has title under this clause is reported in writing to the Contracting Officer.

(5) In order to acquire for its own use or dispose of property to which title is vested in the Government under this clause, the Contractor shall obtain the Contracting Officer's advance approval of the action and the terms. If approved, the basis for payment (the events or performance criteria) to which the property is related shall be deemed to be not in compliance with the terms of the contract and not payable (if the property is part of or needed for performance), and the Contractor shall refund the related performance-based payments in accordance with paragraph (d) of this clause.

(6) When the Contractor completes all of the obligations under this contract, including liquidation of all performance-based payments, title shall vest in the Contractor for all property (or the proceeds thereof) not --

(i) Delivered to, and accepted by, the Government under this contract; or

(ii) Incorporated in supplies delivered to, and accepted by, the Government under this contract and to which title is vested in the Government under this clause.

(7) The terms of this contract concerning liability for Government-furnished property shall not apply to property to which the Government acquired title solely under this clause.

(g) Risk of loss. Before delivery to and acceptance by the Government, the Contractor shall bear the risk of loss for property, the title to which vests in the Government under this clause, except to the extent the Government expressly assumes the risk. If any property is lost (see 45.101), the basis of payment (the events or performance criteria) to which the property is related shall be deemed to be not in compliance with the terms of the contract and not payable (if the property is part of or needed for performance), and the Contractor shall refund the related performance-based payments in accordance with paragraph (d) of this clause.

(h) Records and controls. The Contractor shall maintain records and controls adequate for administration of this

clause. The Contractor shall have no entitlement to performance-based payments during any time the Contractor's records or controls are determined by the Contracting Officer to be inadequate for administration of this clause.

(i) Reports and Government access. The Contractor shall promptly furnish reports, certificates, financial statements, and other pertinent information requested by the Contracting Officer for the administration of this clause and to determine that an event or other criterion prompting a financing payment has been successfully accomplished. The Contractor shall give the Government reasonable opportunity to examine and verify the Contractor's records and to examine and verify the Contractor's performance of this contract for administration of this clause.

(j) Special terms regarding default. If this contract is terminated under the Default clause,

(1) the Contractor shall, on demand, repay to the Government the amount of unliquidated performance-based payments, and

(2) title shall vest in the Contractor, on full liquidation of all performance-based payments, for all property for which the Government elects not to require delivery under the Default clause of this contract. The Government shall be liable for no payment except as provided by the Default clause.

(k) Reservation of rights.

(1) No payment or vesting of title under this clause shall --

(i) Excuse the Contractor from performance of obligations under this contract; or

(ii) Constitute a waiver of any of the rights or remedies of the parties under the contract.

(2) The Government's rights and remedies under this clause --

(i) Shall not be exclusive, but rather shall be in addition to any other rights and remedies provided by law or this contract; and

(ii) Shall not be affected by delayed, partial, or omitted exercise of any right, remedy, power, or privilege, nor shall such exercise or any single exercise preclude or impair any further exercise under this clause or the exercise of any other right, power, or privilege of the Government.

(l) Content of Contractor's request for performance-based payment. The Contractor's request for performance-based payment shall contain the following:

(1) The name and address of the Contractor;

(2) The date of the request for performance-based payment;

(3) The contract number and/or other identifier of the contract or order under which the request is made;

(4) Such information and documentation as is required by the contract's description of the basis for payment; and

(5) A certification by a Contractor official authorized to bind the Contractor, as specified in paragraph (m) of this clause.

(m) Content of Contractor's certification. As required in paragraph (l)(5) of this clause, the Contractor shall make the following certification in each request for performance-based payment:

I certify to the best of my knowledge and belief that --

(1) This request for performance-based payment is true and correct; this request (and attachments) has been prepared

from the books and records of the Contractor, in accordance with the contract and the instructions of the Contracting Officer;

(2) (Except as reported in writing on _____), all payments to subcontractors and suppliers under this contract have been paid, or will be paid, currently, when due in the ordinary course of business;

(3) There are no encumbrances (except as reported in writing on _____) against the property acquired or produced for, and allocated or properly chargeable to, the contract which would affect or impair the Government's title;

(4) There has been no materially adverse change in the financial condition of the Contractor since the submission by the Contractor to the Government of the most recent written information dated _____; and

(5) After the making of this requested performance-based payment, the amount of all payments for each deliverable item for which performance-based payments have been requested will not exceed any limitation in the contract, and the amount of all payments under the contract will not exceed any limitation in the contract.

(End of Clause)

(End of Summary of Changes)

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT				1 CONTRACT ID CODE J	PAGE OF PAGES 1 10
2 AMENDMENT/MODIFICATION NO P00002	3 EFFECTIVE DATE 14-Jul-2020	4 REQUISITION/PURCHASE REQ NO 0011506457		5 PROJECT NO (If applicable)	
6 ISSUED BY US ARMY ACC-APG-RTP W911NF 800 PARK OFFICE DRIVE SUITE 4229 RESEARCH TRIANGLE PARK NC 27709	CODE W911NF	7 ADMINISTERED BY (If other than item 6) DCMA HUNTSVILLE 1040 RESEARCH BLVD SUITE 100 MADISON AL 35758-2040		CODE S0107A	SCD: C
8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code) SIO2 MEDICAL PRODUCTS, NC. 2250 R LEY ST AUBURN AL 36832-8070				9A. AMENDMENT OF SOLICITATION NO.	
				9B. DATED (SEE ITEM 11)	
				X 10A. MOD. OF CONTRACT/ORDER NO. W911NF2030003	
				X 10B. DATED (SEE ITEM 13) 05-Jun-2020	
CODE 8KP08		FACILITY CODE			
11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS					
<input type="checkbox"/> The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of offer <input type="checkbox"/> is extended, <input type="checkbox"/> is not extended. 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)					
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.					
X B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).					
C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:					
D. OTHER (Specify type of modification and authority)					
E. IMPORTANT: Contractor <input checked="" type="checkbox"/> is not, <input type="checkbox"/> is required to sign this document and return _____ copies to the issuing office.					
14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.) Modification Control Number: (b) (6) SEE CONTINUATION PAGES					
Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect					
15A. NAME AND TITLE OF SIGNER (Type or print)			16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) (b) (6) / CONTRACTING OFFICER TEL: (b) (6) EMAIL: (b) (6)		
15B. CONTRACTOR/OFFEROR (Signature of person authorized to sign)		15C. DATE SIGNED	16B. UNITED STATES OF AMERICA BY (b) (6) (Signature of Contracting Officer)		16C. DATE SIGNED 14-Jul-2020

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:

MODIFICATION 2

This document constitutes **Modification P00002** to Technology Investment Agreement W911NF-20-3-003, SIO2 Medical Products Inc.

The purpose of this modification is to: (1) Add the Defense Priorities and Allocations System rating of DO-H5 to this Agreement in accordance with 15 CFR 700 and the rating authorization from Department of Commerce to Department of Defense dated 8 July 2020; (2) Change the address of the Administrative Office in Block 6 of the cover sheet of the Agreement to the Issuing Office Address and; (3) Clarify the Financial Management and Payment Instructions in Article 5 of the Basic Agreement. Therefore, the following changes are hereby incorporated:

1. This Agreement is hereby rated DO-H5 in accordance with 15 CFR 700 and Special Priorities Assistance (SPA) from OUSD/A&S/INDPOL dated July 2, 2020. It is issued under the authority of Section 101 of the Defense Production Act of 1950 (50 U.S.C. § 4501, et seq.) and the DPAS regulation, and with the program determinations by DHS/FEMA dated April 20, 2020 and May 8, 2020.
 - a. The elements required for all rated orders are as follows:
 - i. Appropriate Priority Rating and Program Identification Symbol: **DO-H5**
 - ii. Required Delivery Dates/Period of Performance: **05 June 2020-04 June 2023**
 - iii. Written signature: **provided in the original agreement.**
 - iv. Statement: **This is a rated order certified for national defense use and you are required to follow all the provisions of the Defense Priorities and Allocations System regulations (15 CFR part 700)**
 - v. Additional element for emergency preparedness: **This rated order is placed for the purpose of emergency preparedness. It must be accepted or rejected within 15 working days of receipt of order. This language shall flow down to subawards for Industrial Resources-Services only.**
 - b. Definitions:
 - i. "Industrial Resources" means materials, services, processes, or manufacturing equipment (including the processes, technologies, and ancillary services for the use of such equipment) needed to establish or maintain an efficient and modern national defense industrial base.
 - ii. "Materials" includes –
 1. any raw materials (including minerals, metals, and advanced processed materials), commodities, articles, components (including critical components), products, and items of supply; and
 2. "Health resources" means drugs, biological products, medical devices, materials, facilities, health supplies, services and equipment required to diagnose, mitigate or prevent the impairment of, improve, treat, cure, or restore the physical or mental health conditions of the population.
 3. any technical information or services ancillary to the use of any such materials, commodities, articles, components, products, or items.
 - iii. "Services" includes any effort that is needed for or incidental to –
 1. the development, production, processing, distribution, delivery, or use of an industrial resource or a critical technology item;
 2. the construction of facilities;

3. the movement of individuals and property by all modes of civil transportation;
Or
 4. other national defense programs and activities.
- iv. "Health resources" means drugs, biological products, medical devices, materials, facilities, health supplies, services and equipment required to diagnose, mitigate or prevent the impairment of, improve, treat, cure, or restore the physical or mental health conditions of the population
- c. **The DPAS rating is to be used only for Industrial Resources – Services and not for Health Resources as defined above.**

2. **Article 4, Program/Administrative Management, SubArticle 4.2 Government Representatives,**

(b) (6)

A large rectangular area of the document is redacted with black ink. The redaction covers several lines of text, starting from the left margin and extending across most of the page width. The text "(b) (6)" is written in red at the top left of this redacted area.

NOTE: The BARDA Program Manager and/or members of his team will be responsible for conducting all oversight reviews indicated in Article 16.2, "Quarterly-In-Process Reviews"

3. **Article 5, Financial Management and Payment shall be changed to read as follows:**

TO:

5. Financial Management & Payment

5.1 Fixed Support.

This Agreement is a fixed-support type Technology Investment Agreement (TIA) as described in 32 CFR §37.300. Fixed-support means that the amount of assistance established at the time of award is not meant to be adjusted later if the research project is carried out to completion. Payments will be based on Payable Milestones as defined in 32 CFR 37.815. These are payments made according to a schedule that is based on predetermined measures of technical progress or other payable milestones. This approach relies upon the fact that, as research progresses throughout the term of the agreement, observable activity will be taking place. The Recipient is paid upon the accomplishment of the predetermined measure of progress. Post-award administrators may adjust amounts of future milestone payments if a project's expenditures fall too far below the projections that were the basis for setting the amounts (*see* §37.575(c) and §37.1105(c)).

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 of milestone acceptance via 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 2-in-1.

(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*

Pay Official DoDAAC	HQ0338
Issue By DoDAAC	W911NF
Admin DoDAAC	S0107A
Ship From Code N/A	
Mark For Code N/A	
Service Approver DoDAAC	S0107A
Accept at Other DoDAAC	N/A
LPO DoDAAC	N/A
DCAA Auditor DoDAAC	N/A

Other DoDAAC(s)	N/A
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(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.
- (2) Technical WAWF help, contact the WAWF helpdesk at 866-618-5988.

The following have been deleted:

MODIFICATION

SECTION A - SOLICITATION/CONTRACT FORM

The DPAS code DO-H5 has been added.

SECTION B - SUPPLIES OR SERVICES AND PRICES

The following have been deleted:

52.232-32 Performance-Based Payments APR 2012

SECTION F - DELIVERIES OR PERFORMANCE

The following Delivery Schedule item for CLIN 0001 has been changed from:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
POP 05-JUN-2020 TO 04-JUN-2021	N/A	JPM MEDICAL JPM MEDICAL 1564 FREEDMAN DRIVE FORT DETRICK, MD MD 21702 FOB: Destination	W56XNH

To:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
POP 05-JUN-2020 TO 04-JUN-2021	N/A	CHEMICAL BIOLOGICAL MEDICAL CENTER (CBMS CHEMICAL BIOLOGICAL MEDICAL CENTER 1564 FREEDMAN DRIVE 1564 FREEDMAN DRIVE FORT DETRICK MD 21702 (b) (6) FOB: Destination	W56XNH

The following Delivery Schedule item for CLIN 0002 has been changed from:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
POP 05-JUN-2021 TO 04-JUN-2022	N/A	N/A FOB: Destination	

To:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
POP 05-JUN-2021 TO 04-JUN-2022	N/A	CHEMICAL BIOLOGICAL MEDICAL CENTER (CBMS CHEMICAL BIOLOGICAL MEDICAL CENTER 1564 FREEDMAN DRIVE 1564 FREEDMAN DRIVE FORT DETRICK MD 21702 (b) (6) FOB: Destination	W56XNH

The following Delivery Schedule item for CLIN 0003 has been changed from:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
POP 05-JUN-2022 TO 04-JUN-2023	N/A	N/A FOB: Destination	

To:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
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POP 05-JUN-2022 TO 04-JUN-2023	N/A	CHEMICAL BIOLOGICAL MEDICAL CENTER (CBMS CHEMICAL BIOLOGICAL MEDICAL CENTER 1564 FREEDMAN DRIVE 1564 FREEDMAN DRIVE FORT DETRICK MD 21702 (b) (6) FOB: Destination	W56XNH
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The following Delivery Schedule item for CLIN 0004 has been changed from:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
POP 05-JUN-2023 TO 04-JUN-2024	N/A	N/A FOB: Destination	

To:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
POP 05-JUN-2023 TO 04-JUN-2024	N/A	CHEMICAL BIOLOGICAL MEDICAL CENTER (CBMS CHEMICAL BIOLOGICAL MEDICAL CENTER 1564 FREEDMAN DRIVE 1564 FREEDMAN DRIVE FORT DETRICK MD 21702 (b) (6) FOB: Destination	W56XNH

The following Delivery Schedule item for CLIN 0005 has been changed from:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
POP 05-JUN-2024 TO 04-JUN-2025	N/A	N/A FOB: Destination	

To:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
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POP 05-JUN-2024 TO 04-JUN-2025	N/A	CHEMICAL BIOLOGICAL MEDICAL CENTER (CBMS CHEMICAL BIOLOGICAL MEDICAL CENTER 1564 FREEDMAN DRIVE 1564 FREEDMAN DRIVE FORT DETRICK MD 21702 (b) (6) FOB: Destination	W56XNH
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The following Delivery Schedule item for CLIN 0006 has been changed from:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
POP 05-JUN-2025 TO 04-JUN-2026	N/A	N/A FOB: Destination	

To:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
POP 05-JUN-2025 TO 04-JUN-2026	N/A	CHEMICAL BIOLOGICAL MEDICAL CENTER (CBMS CHEMICAL BIOLOGICAL MEDICAL CENTER 1564 FREEDMAN DRIVE 1564 FREEDMAN DRIVE FORT DETRICK MD 21702 (b) (6) FOB: Destination	W56XNH

The following Delivery Schedule item for CLIN 0007 has been changed from:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
POP 05-JUN-2026 TO 04-JUN-2027	N/A	N/A FOB: Destination	

To:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE

POP 05-JUN-2026 TO 04-JUN-2027	N/A	CHEMICAL BIOLOGICAL MEDICAL CENTER (CBMS CHEMICAL BIOLOGICAL MEDICAL CENTER 1564 FREEDMAN DRIVE 1564 FREEDMAN DRIVE FORT DETRICK MD 21702 (b) (6) FOB: Destination	W56XNH
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The following Delivery Schedule item for CLIN 0008 has been changed from:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
POP 05-JUN-2027 TO 04-JUN-2028	N/A	N/A FOB: Destination	

To:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
POP 05-JUN-2027 TO 04-JUN-2028	N/A	CHEMICAL BIOLOGICAL MEDICAL CENTER (CBMS CHEMICAL BIOLOGICAL MEDICAL CENTER 1564 FREEDMAN DRIVE 1564 FREEDMAN DRIVE FORT DETRICK MD 21702 (b) (6) FOB: Destination	W56XNH

The following Delivery Schedule item for CLIN 0009 has been changed from:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
POP 05-JUN-2028 TO 04-JUN-2029	N/A	N/A FOB: Destination	

To:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
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POP 05-JUN-2028 TO 04-JUN-2029	N/A	CHEMICAL BIOLOGICAL MEDICAL CENTER (CBMS CHEMICAL BIOLOGICAL MEDICAL CENTER 1564 FREEDMAN DRIVE 1564 FREEDMAN DRIVE FORT DETRICK MD 21702 (b) (6) FOB: Destination	W56XNH
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The following Delivery Schedule item for CLIN 0010 has been changed from:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
POP 05-JUN-2029 TO 04-JUN-2030	N/A	N/A FOB: Destination	

To:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
POP 05-JUN-2029 TO 04-JUN-2030	N/A	CHEMICAL BIOLOGICAL MEDICAL CENTER (CBMS CHEMICAL BIOLOGICAL MEDICAL CENTER 1564 FREEDMAN DRIVE 1564 FREEDMAN DRIVE FORT DETRICK MD 21702 (b) (6) FOB: Destination	W56XNH

(End of Summary of Changes)

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT			1 CONTRACT ID CODE	PAGE OF PAGES
			J	1 15
2 AMENDMENT/MODIFICATION NO P00003	3 EFFECTIVE DATE 13-Aug-2020	4 REQUISITION/PURCHASE REQ NO 0011506457	5 PROJECT NO (If applicable)	
6 ISSUED BY US ARMY ACC-APG-RTP W911NF 800 PARK OFFICE DRIVE SUITE 4229 RESEARCH TRIANGLE PARK NC 27709	CODE W911NF	7 ADMINISTERED BY (If other than item 6) DCMA HUNTSVILLE 1040 RESEARCH BLVD SUITE 100 MADISON AL 35758-2040	CODE S0107A	SCD: C
8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code) SIO2 MEDICAL PRODUCTS, NC. 2250 R LEY ST AUBURN AL 36832-8070			9A. AMENDMENT OF SOLICITATION NO.	
			9B. DATED (SEE ITEM 11)	
			X 10A. MOD. OF CONTRACT/ORDER NO. W911NF2030003	
			X 10B. DATED (SEE ITEM 13) 05-Jun-2020	
CODE 8KP08	FACILITY CODE			
11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS				
<input type="checkbox"/> The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of offer <input type="checkbox"/> is extended, <input type="checkbox"/> is not extended.				
<p>Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods:</p> <p>(a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.</p>				
12. ACCOUNTING AND APPROPRIATION DATA (If required)				
13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF 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).				
X C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: Article 17				
D. OTHER (Specify type of modification and authority)				
E. IMPORTANT: Contractor <input type="checkbox"/> is not, <input checked="" type="checkbox"/> 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) SEE CONTINUATION PAGES				
Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect				
15A. NAME AND TITLE OF SIGNER (Type or print)			16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)	
			(b) (6) / CONTRACTING OFFICER	
			TEL: (b) (6) EMAIL: (b) (6)	
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA		16C. DATE SIGNED
(Signature of person authorized to sign)		BY (b) (6)		18-Aug-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:

MODIFICATION 3

This document constitutes **Modification P00003** to Technology Investment Agreement W911NF-20-3-003, SIO2 Medical Products Inc.

The purpose of this modification is to: (1) change Article 17 of the Agreement and; (2) add Appendix 1 to the Agreement. The Agreement is hereby modified as follows:

1. **Article 17, Modification to the Agreement is changed to read as follows:**

FROM

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 Agreement Officer be effective or binding upon the Government. All such actions must be formalized by a proper contractual document executed by the Agreement Officer. The only method by which this Agreement can be modified is by a formal, written modification signed by the Agreements Officer. No other communications, whether oral or in writing, shall modify this Agreement.

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

TO:

Section 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 Agreement Officer or the Administrative Agreements Officer be effective or binding upon the Government. The Administrative Agreements Officer shall have express authorization from the Agreements Officer when issuing other than unilateral or minor modifications, as identified in 17.3 of this section. All such actions must be formalized by a proper contractual document executed by the Agreement Officer or the Administrative Agreements Officer. The only method by which this Agreement can be modified is by a formal, written modification signed by the

Agreements Officer or the Administrative Agreements Officer. No other communications, whether oral or in writing, shall modify this Agreement.

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

17.3 Unilateral or Minor. The AO or AAO 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.

2. Appendix 1 is hereby incorporated into the Agreement as follows:

Appendix 1 Clause for all other Other Transaction Authority Agreements

Standard OWS-SA Language for DoD OT Based Contracts

Supply Chain Resiliency Plan

The contractor shall develop and submit within 30 calendar days of 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 Officer or the Contracting 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 of contract 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

Language for Security Section (or Similar)**Access and General Protection/Security Policy and Procedures**

This standard language text is applicable to ALL employees working on critical information related to Operation Warp Speed (OWS), and to those with an area of performance within a Government controlled installation, facility or area. Employees shall comply with applicable installation, facility and area commander installation/facility access and local security policies and procedures (provided by government representative). The performer also shall provide all information required for background checks necessary to access critical information related to OWS, and to meet Government installation access requirements to be accomplished by installation Director of Emergency Services or Security Office. The workforce must comply with all personnel identity verification requirements as directed by the Government and/or local policy. In addition to the changes otherwise authorized by the changes clause of this agreement, should the security status of OWS change the Government may require changes in performer security matters or processes. 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.

Operational Security (OPSEC)

The performer shall develop an OPSEC Standard Operating Procedure (SOP)/Plan within ninety (90)-calendar-days of project award to be reviewed and approved by the responsible Government OPSEC officer. This plan will be submitted to the COR for coordination of approvals. This SOP/Plan will include identifying the critical information related to this contract, why it needs to be protected, where it is located, who is responsible for it, and how to protect it.

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 Government 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 Government for review and approval by Government security subject matter experts. The performance of work under the contract will be in accordance with the approved security plan. The security plan will include the following processes and procedures at a minimum:	
Security Administration	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • identification and marking of sensitive information • access control • storage of information • document control procedures • retention/ destruction requirements
Information Technology/Cyber Security Policies and Procedures	<ul style="list-style-type: none"> • 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

	<ul style="list-style-type: none"> • system document control • system backup • system disaster recovery • incident response • system audit procedures • property accountability
<p>2. Site Security Master Plan</p> <p>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.</p>	
<p>3. Site Threat / Vulnerability / Risk Assessment</p> <p>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.</p>	
<p>4. Physical Security</p> <p>Description:</p>	
Closed Circuit Television (CCTV) Monitoring	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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.

	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> a) Conduct new employee security awareness training. b) Conduct and maintain records of annual security awareness training.
Security Management	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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 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. <ul style="list-style-type: none"> • 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 Government 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.

Language for SOW Other Requirements Section (or Similar)

Key Personnel

Any key personnel specified in this contract 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 contracts the Contractor shall notify the Contracting Officer and shall submit a justification for the diversion or replacement and a request to replace the individual. The request must identify the proposed replacement and provide an explanation of how the replacement's skills, experience, and credentials meet or exceed the requirements of the contract (including, when applicable, Human Subjects Testing requirements). If the employee of the 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 Contracting Officer. The contract 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:

Substitution of Key Personnel

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

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

Disclosure of Information

Performance under this contract 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 contract, except authorized by Government personnel or upon written approval of the CO in accordance with OWS or other Government policies and/or guidance. The Contractor shall not use, disclose, or reproduce proprietary data that bears a restrictive legend, other than as specified in this contract, or any information at all regarding this agency.

The Contractor shall comply with all Government requirements for protection of non-public information. Unauthorized disclosure of nonpublic information is prohibited by the Government's rules. Unauthorized disclosure may result in termination of the contract, 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.

No information related to data obtained under this contract 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.

Publications and Publicity

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

(a) Unless otherwise specified in this contract, the contractor may publish the results of its work under this contract. 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 CO, the contractor shall not display Government logos 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 contract in commercial advertising, as defined in FAR 31.205-1, in any manner which states or implies Government approval or endorsement of the product(s) or service(s) provided.

(d) The 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 Government whenever publicizing the work under this contract in any media by including an acknowledgement substantially as follows:

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

Confidentiality of Information

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

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

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

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

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

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

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

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

Organizational Conflicts of Interest

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

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

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

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

Institutional Responsibility Regarding Investigator Conflicts of Interest

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

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

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

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

Significant financial interests do not include the following:

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

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

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

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

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

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

- g. Provide initial and ongoing FCOI reports to the Contracting Officer pursuant to Part 94.5(b).
- h. Maintain records relating to all Investigator disclosures of financial interests and the Institution's review of, and response to, such disclosures, and all actions under the Institution's policy or retrospective review, if applicable, for at least 3 years from the date of final payment or, where applicable, for the other time periods specified in 48 CFR Part 4, subpart 4.7, Contract Records Retention.
- i. Establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator compliance as appropriate.
- j. Complete the certification in Section K - Representations, Certifications, and Other Statements of Contractors titled "Certification of Institutional Policy on Financial Conflicts of Interest".

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

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

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

The following have been deleted:

MODIFICATION 2

(End of Summary of Changes)