AWARD/CONTRACT

1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)	RATING	PAGE OF PAGES
		1 | 30

2. CONTRACT (Proc. Inst. Ident.) NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQUEST/PROJECT NO.
W911SR2030004	01 Jul 2020	0011506626-0001

5. ISSUED BY	CODE	6. ADMINISTERED BY (If other than Item 5)	CODE
US ARMY RDECOM CONTRACTING CMD APG, EDGEWOOD CONTRACTING DIVISION E4455 LEITZAN ROAD ABERRDEEN PROVING GROUND MD 21010-5401	W911SR	DCMA DALLAS - S4402A 500 NORTH PEARL STREET SUITE 1630 DALLAS TX 75201-2843	S4402A

7. NAME AND ADDRESS OF CONTRACTOR (No., street, city, county, state and zip code)	8. DELIVERY	9. DISCOUNT FOR PROMPT PAYMENT	10. SUBMIT INVOICES (4 copies unless otherwise specified) TO THE ADDRESS SHOWN IN:	ITEM
RETRACTABLE TECHNOLOGIES, INC. 511 LOBO LN LITTLE ELM TX 75068-5295	[ ] FOB ORIGIN [X] OTHER (See below)	Net 30 Days		

CODE 1BFK3	FACILITY CODE

11. SHIP TO/MARK FOR	CODE	12. PAYMENT WILL BE MADE BY	CODE
BIOMEDICAL ADVANCED RESEARCH DEVELOPMENT (b) (6) ROOM 23E07 O'NEILL HOUSE OFFICE BUILDING WASHINGTON DC 20515	W6QNH	DFAS-COLUMBUS CENTER DFAS-COWEST ENTITLEMENT OPERATIONS P.O. BOX 182381 COLUMBUS OH 43218-2381	HQ0339

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

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

15G. TOTAL AMOUNT OF CONTRACT (b) (4)

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CONTRACTING OFFICER WILL COMPLETE ITEM 17 (SEALED-BID OR NEGOTIATED PROCUREMENT) OR 18 (SEALED-BID PROCUREMENT) AS APPLICABLE

17. [X] CONTRACTOR'S NEGOTIATED AGREEMENT (Contractor is required to sign this document and return 1 copies to issuing office.) Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any continuation sheets for the consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the following documents: (a) this award/contract, (b) the solicitation, if any, and (c) such provisions, representations, certifications, and specifications, as are attached or incorporated by reference herein. (Attachments are listed herein.)

18. [ ] SEALED-BID AWARD (Contractor is not required to sign this document.)
Your bid on Solicitation Number _____
including the additions or changes made by you which additions or changes are set forth in full above, is hereby accepted as to the terms listed above and on any continuation sheets. This award consummates the contract which consists of the following documents: (a) the Government's solicitation and your bid, and (b) this award/contract. No further contractual document is necessary. (Block 18 should be checked only when awarding a sealed-bid contract.)

19A. NAME AND TITLE OF SIGNER (Type or print)	20A. NAME OF CONTRACTING OFFICER
(b) (6)	(b) (6) TEL: (b) (6) EMAIL: (b) (6)

19B. NAME OF CONTRACTOR	19C. DATE SIGNED	20B. UNITED STATES OF AMERICA	20C. DATE SIGNED
BY (b) (6)	7/1/2020	BY (b) (6) (Signature of Contracting Officer)	1 July 2020

Section B - Supplies or Services and Prices

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0001			(b) (4)		(b) (4) NTE

TECHNOLOGY INVESTMENT AGREEMENT
COST

Technology Investment Agreement (TIA) for Expanding Domestic Production of Needles & Syringes IAW vendor project plan dated (b) (4)

FOB: Destination
PURCHASE REQUEST NUMBER: (b) (4)
PSC CD: (b) (4)

ESTIMATED COST (b) (4)

ACRN AA
CIN: (b) (4)

INSPECTION AND ACCEPTANCE TERMS

Supplies/services will be inspected/accepted at:

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

Section F - Deliveries or Performance

F.1 Supply Chain Resiliency Plan

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

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

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

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

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

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

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

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

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

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

DELIVERY INFORMATION

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

FOB: Destination

Section G - Contract Administration Data

ACCOUNTING AND APPROPRIATION DATA

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

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

Section H - Special Contract Requirements

H.1 Key Personnel

H.1.1 Pursuant to HHSAR 352.237-75 (Dec 2015), Key Personnel, any key personnel specified in this agreement are considered to be essential to work performance. At least thirty (30) calendar days prior to the Contractor voluntarily diverting any of the specified individuals to other programs or agreements the Contractor shall notify the Agreements Officer and shall submit a justification for the diversion or replacement and a request to replace the individual. The request must identify the proposed replacement and provide an explanation of how the replacement's skills, experience, and credentials meet or exceed the requirements of the agreement (including, when applicable, Human Subjects Testing requirements). If the employee of the Contractor is terminated for cause or separates from the Contractor voluntarily with less than thirty (30) calendar-day notice, the Contractor shall provide the maximum notice practicable under the circumstances. The Contractor shall not divert, replace, or announce any such change to key personnel without the written consent of the Agreements Officer. The agreement will be modified to add or delete key personnel as necessary to reflect the agreement of the parties. The following individuals are determined to be key personnel:

H.1.2 Substitution of Key Personnel

H.1.2.1 The Contractor agrees to assign to the agreement those persons whose resumes/CVs were submitted with the proposal who are necessary to fill the requirements of the agreement. No substitutions shall be made except in accordance with this clause.

H.1.2.2 All requests for substitution must provide a detailed explanation of the circumstance necessitating the proposed substitution, a complete resume for the proposed substitute and any other information requested by the Agreements Officer to approve or disapprove the proposed substitution. All proposed substitutes must have qualifications that are equal to or higher than the qualifications of the person to be replaced. The Agreements Officer or authorized representative will evaluate such requests and promptly notify the contractor of his approval or disapproval thereof.

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

H.2 Disclosure of Information:

H.2.1 Performance under this agreement may require the Contractor to access non-public data and information proprietary to a Government agency, another Government Contractor or of such nature that its dissemination or use other than as specified in the work statement would be adverse to the interests of the Government or others. Neither the Contractor, nor Contractor personnel, shall divulge nor release data nor information developed or obtained under performance of this agreement, except authorized by Government personnel or upon written approval of the CO. The Contractor shall not use, disclose, or reproduce proprietary data that bears a restrictive legend, other than as specified in this agreement, or any information at all regarding this agency.

H.2.2 Consistent with HHS Directive 1139, the Contractor shall comply with HHS requirements for protection of non-public information. Unauthorized disclosure of nonpublic information is prohibited by the HHS's rules. Unauthorized disclosure may result in termination of the agreement, replacement of a Contractor employee, or other appropriate redress. Neither the Contractor nor the Contractor's employees shall disclose or cause to be disseminated, any information concerning the operations of the activity, which could result in, or increase the likelihood of, the possibility of a breach of the activity's security or interrupt the continuity of its operations.

H.2.3 No information related to data obtained under this agreement shall be released or publicized without the prior written consent of the COR, whose approval shall not be unreasonably withheld, conditioned, or delayed, provided that no such consent is required to comply with any law, rule, regulation, court ruling or similar order; for submission to any government entity' for submission to any securities exchange on which the Contractor's (or its

parent corporation's) securities may be listed for trading; or to third parties relating to securing, seeking, establishing or maintaining regulatory or other legal approvals or compliance, financing and capital raising activities, or mergers, acquisitions, or other business transactions.

H.3 Confidentiality of Information

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

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

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

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

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

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

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

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

H.4 Organizational Conflicts of Interest:

H.4.1 Performance under this agreement may create an actual or potential organizational conflict of interest such as are contemplated by FAR Part 9.505-General Rules. The Contractor shall not engage in any other contractual or other activities which could create an organizational conflict of interest (OCI). This provision shall apply to the prime Contractor and all sub-Contractors. This provision shall have effect throughout the period of performance of this agreement, any extensions thereto by change order or supplemental agreement, and for two (2) years thereafter. The Government may pursue such remedies as may be permitted by law or this agreement, upon determination that an OCI has occurred.

H.4.2 The work performed under this agreement may create a significant potential for certain conflicts of interest, as set forth in FAR Parts 9.505-1, 9.505-2, 9.505-3, and 9.505-4. It is the intention of the parties hereto to prevent both the potential for bias in connection with the Contractor's performance of this agreement, as well as the creation of any unfair competitive advantage as a result of knowledge gained through access to any non-public data or third party proprietary information.

H.4.3 The Contractor shall notify the Agreements Officer immediately whenever it becomes aware that such access or participation may result in any actual or potential OCI. Furthermore, the Contractor shall promptly submit a plan to the Agreements Officer to either avoid or mitigate any such OCI. The Agreements Officer will have sole

discretion in accepting the Contractor's mitigation plan. In the event the Agreements Officer unilaterally determines that any such OCI cannot be satisfactorily avoided or mitigated, other remedies may be taken to prohibit the Contractor from participating in agreement requirements related to OCI.

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

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

H.5 Operations Security (OPSEC)

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

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

H.6 Security

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

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

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

BARDA SECUIRTY REQUIREMENTS

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

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

Description: The partner facility shall provide a written risk assessment for the facility addressing: criminal threat, including crime data; foreign/domestic terrorist threat; industrial espionage; insider threats; natural disasters; and potential loss of critical infrastructure (power/water/natural gas, etc.) This assessment shall include recent data obtained from local law enforcement agencies. The assessment should be updated annually.	
4. Physical Security Description:	
Closed Circuit Television (CCTV) Monitoring	a) Layered (internal/external) CCTV coverage with time-lapse video recording for buildings and areas where critical assets are processed or stored. b) CCTV coverage must include entry and exits to critical facilities, perimeters, and areas within the facility deemed critical to the execution of the agreement. c) Video recordings must be maintained for a minimum of 30 days. d) CCTV surveillance system must be on emergency power backup. e) CCTV coverage must include entry and exits to critical facilities, perimeters, and areas within the facility deemed critical to the execution of the agreement. f) Video recordings must be maintained for a minimum of 30 days. g) CCTV surveillance system must be on emergency power backup.
Facility Lighting	a) Lighting must cover facility perimeter, parking areas, critical infrastructure, and entrances and exits to buildings. b) Lighting must have emergency power backup. c) Lighting must be sufficient for the effective operation of the CCTV surveillance system during hours of darkness.
Shipping and Receiving	a) Must have CCTV coverage and an electronic access control system. b) Must have procedures in place to control access and movement of drivers picking up or delivering shipments. c) Must identify drivers picking up BARDA products by government issued photo identification.
Access Control	a) Must have an electronic intrusion detection system with centralized monitoring. b) Responses to alarms must be immediate and documented in writing. c) Employ an electronic system (i.e., card key) to control access to areas where assets critical to the agreement are located (facilities, laboratories, clean rooms, production facilities, warehouses, server rooms, records storage, etc.). d) The electronic access control should signal an alarm notification of unauthorized attempts to access restricted areas. e) Must have a system that provides a historical log of all key access transactions and kept on record for a minimum of12 months. f) Must have procedures in place to track issuance of access cards to employees and the ability to deactivate cards when they are lost or an employee leaves the company. g) Response to electronic access control alarms must be immediate and documented in writing and kept on record for a minimum of 12 months. h) Should have written procedures to prevent employee piggybacking access i) to critical infrastructure (generators, air handlers, fuel storage, etc.) should be controlled and limited to those with a legitimate need for access. j) Must have a written manual key accountability and inventory process. k) Physical access controls should present a layered approach to critical assets within the facility.

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

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

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

Section I - Contract Clauses

TERMS & CONDITIONS

TECHNOLOGY INVESTMENT AGREEMENT

between

Retractable Technologies, Inc. (RTI)

and

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

on behalf of

Biomedical Advanced Research and Development Authority (BARDA)

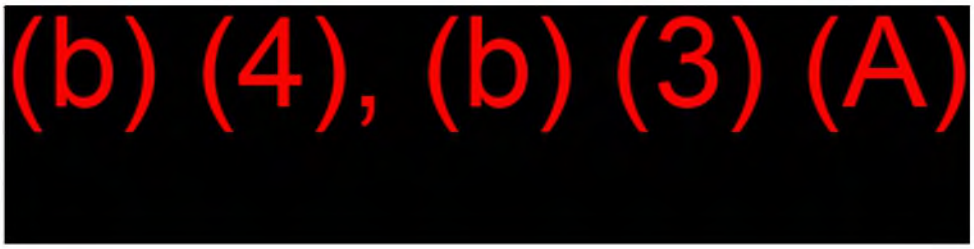
for

Expanding Domestic Production of Needles & Syringes

Agreement No.:W911SR2030004
Total Amount of Government Funding for the Agreement: (b) (4)
Total Cost Share for the Agreement: (b) (4)
Total Estimated Value of the Agreement: (b) (4)
Effective Date: 01 JUL 2020

TECHNOLOGY INVESTMENT AGREEMENT TERMS AND CONDITIONS

ARTICLES



RECITALS

This Agreement is entered into between the United States of America, Department of Defense, represented by ACC-APG, NCD & ECD ("Government") and Retractable Technologies, Inc. (RTI), ("Recipient"), collectively referred to as the "Parties," pursuant to and under the statutory authority at 10 U.S.C. §2371 and/or 10 U.S.C. §2358.

The Recipient, a for-profit firm, submitted a basic, applied, or advanced research proposal to the Government in response to the publicly disseminated Medical Countermeasures System (MCS) Broad Agency Announcement (BAA) 17-01. The proposal was identified within the MCS BAA scope of: Advanced Development & Manufacturing Capabilities (ADMC), to develop a national capability and capacity to develop and produce medical countermeasures rapidly to counter known or unknown chemical, biological, radioactive, and nuclear (CBRN) threats, including novel and previously unrecognized, naturally- occurring emerging infectious diseases such as the COVID-19 virus. The specific MCS BAA Area of Interest is Mission Area 1, Medical Biological Prophylaxis.

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

THEREFORE, THE PARTIES AGREE:

1. Scope of Agreement

1.1 Governing Authority

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

1.2 Principal Purpose

The Government and the Recipient agree that the principal purpose of this Agreement is for Government investment into the development/expansion of Recipient's manufacturing capacity for hypodermic safety needles and corresponding syringes in response to the worldwide Coronavirus (COVID-19) global pandemic (b) (4) [redacted] This Agreement is not intended to be, nor shall it be construed as, by implication or otherwise, a partnership, a

corporation, or other business organization.

2. Term of Agreement

This Agreement shall commence upon the effective date listed on page 1, after execution of the Agreement by both parties, for a period of 10 years, the "term" of the Agreement or "Period of Performance." *Period of performance* means the time during which a recipient or sub-recipient may incur new obligations to carry out the work authorized under an award or sub-award, respectively.

3. Order of Precedence

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

4. Program/Administrative Management

4.1 Program Management

The Recipient has full responsibility for the project/activity supported by this Agreement, in accordance with the Recipient's proposal and proposal revisions/appendices, and the terms and conditions specified in this Agreement. The Government will have continuous and/or substantial involvement with the Recipient pursuant to a Collaboration Plan as incorporated. The Recipient must consult the Program Office/Technical Representative through the Agreements Officer before deviating from the objectives or overall program of the research originally proposed. Non-compliance with any award provision of this clause may result in the withholding of funds and or the termination of the award.

4.2 Government Representatives:

Agreements Officer (AO)

(b) (6)

Agreements Specialist (AS)

(b) (6)

ACC-APG, ECD

8456 Brigade Street

Building E4215

Aberdeen Proving Ground, MD 21010

(b) (6)

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

(b) (6)

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

(b) (6)

(b) (6)

4.3 Recipients Representatives

(b) (6)

5. Financial Management & Payment

5.1 Expenditure-Based.

This Agreement is an expenditure type TIA as described in 32 CFR §37.1285. *Expenditure* is defined in 32 CFR §37.1290. The charges may be reported on a cash or accrual basis, as long as the methodology is disclosed and is consistently applied. In accordance with 32 CFR 37.300(a): "For an expenditure-based TIA, the amounts of interim payments or the total amount ultimately paid to the Recipient are based on the amounts the Recipient expends on project costs. If a Recipient completes the project specified at the time of award before it

expends all of the agreed-upon Federal funding and Recipient cost sharing, the Federal Government may recover its share of the unexpended balance of funds or, by mutual agreement with the Recipient, amend the agreement to expand the scope of the research project. An expenditure-based TIA therefore is analogous to a cost-type procurement contract or grant."

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

5.2 Obligation

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

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

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

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

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

5.3.4. WAWF Provision:

(a) Definitions. As used in this clause--

> Department of Defense Activity Address Code (DoDAAC) is a six position code that uniquely identifies a unit, activity, or organization.
>
> Document type means the type of payment request or receiving report available for creation in Wide Area WorkFlow (WAWF).
>
> Local processing office (LPO) is the office responsible for payment certification when payment certification is done external to the entitlement system.

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

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

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

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

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

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

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

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

Routing Data Table*

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

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

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

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

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

(g) WAWF point of contact.

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

Administrative Grants Officer (AGO)
DCMA DALLAS – S4402A
4211 Cedar Springs Road
Dallas, TX 75219
214-670-9201
(b) (6)

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

6. Accounting & Audit

6.1 Accounting System.

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

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

6.2 Annual Audit Requirement.

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

6.3 Program Income. Program income derived during the initial Period of Performance from Government funding shall be allocated to finance the non-Federal share of the Project (including the amounts described in Section 8.1) in accordance with 32 CFR §34.14(d)(2). As contemplated by 32 CFR §34.14(b)(2), Recipient will have no obligation to the Government for

program income generated after the end of the Period of Performance, and no recovery of funds is contemplated under 32 CFR §37.580.

7. Purchasing & Title

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

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

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

8. Cost Sharing

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

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

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

9. Government Preference

(b) (4)

(b) (4)

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

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

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

10. Records Retention & Government Access

The DoD, Comptroller General of the United States, or any of their duly authorized representatives, have the right of timely and unrestricted access to any books, documents, papers, or other records of the Recipient that are pertinent solely to the Recipient's technical performance under this Agreement, in order to make examinations, excerpts, transcripts and copies of such documents. This right also includes timely and reasonable access to the Recipient's personnel for the purpose of interview and discussion related to such records. Such access shall be performed during business hours on business days upon written notice and shall be subject to the security requirements of the audited Party to the extent such security requirements do not conflict with the rights of access otherwise granted by this paragraph. The rights of access in this paragraph shall last as long as records are retained. The rights of access in this paragraph do not extend to the Recipient's financial records.

11. Intellectual Property & Patent Rights

11.1 Background IP and Materials. The Recipient and the Government each retain any intellectual property (IP) rights to their own materials, data, technology, information, documents, or know-how—or potential rights, such as issued patents, patent applications, invention disclosures, or other written documentation—that exist prior to execution of this

Agreement or are developed outside the scope of this Agreement (Background IP).

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

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

11.4 Patent Applications. Irrespective of any Disclosure of Information clauses in this Agreement the Parties will respectively have the option to file a patent application claiming any Invention made solely by their respective employees. The Parties will consult with each other regarding the options for filing a patent application claiming a joint Invention. Within two (2) months of being notified of the discovery of an invention or filing a patent application covering an Invention, each Party will provide notice of such discovery or filing to the other Party. The Parties will reasonably cooperate with each other in the preparation, filing, and prosecution of any patent application claiming an Invention. Any Party filing a patent application will bear expenses associated with filing and prosecuting the application, as well as maintaining any patents that issue from the application, unless otherwise agreed by the Parties.

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

11.6 Executive Order No. 9424 of 18 February 1944 requires all executive Departments and agencies of the Government to forward through appropriate channels to the Commissioner of Patents and Trademarks, for recording, all Government interests in patents or applications for patents. Should any of these provisions be inconsistent with the Bayh-Dole Act, the statute takes precedence.

12. Data Rights:

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

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

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

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

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

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

13.1 Good Manufacturing Practices (GMP) Compliance. To the extent required under the Federal Food, Drug, and Cosmetic Act, the Recipient will ensure that the manufacturing capability established under this Agreement complies with current good manufacturing practices (cGMPs) under 21 CFR 210 and 211. The Recipient will notify the Government of any written cGMP inspection findings from the FDA pertinent to the manufacturing capability established under this Agreement.

13.2 FDA Communications. The Recipient will provide the Government with summaries of any Recipient formal meetings with the FDA and future correspondence between Recipient and the FDA regarding the manufacturing contemplated under this Agreement and ensure that Government representatives are invited to participate in any Recipient formal meetings with the FDA regarding topics that are material to Recipient's compliance with the terms of this Agreement.

14. Termination

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

15. Disputes

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

16. Reports & Distribution

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

a. Summary of monthly progress for the Recipient's facilities/capabilities associated with this effort

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

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

16.3 Annual Financial Status Report. (37.880)

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

17. Modification of the Agreement

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

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

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

18. Miscellaneous

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

18. 2 Entire Agreement. This Agreement, inclusive of the proposal, proposal revision, proposal appendices, and collaboration plan(s), constitutes the entire Agreement between the Parties concerning the subject matter hereof and supersedes any prior understandings or written or oral Agreement relative to said matter. In the event of a conflict between the terms of this Agreement, the terms of this Agreement shall govern.

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

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

18. 5 Non-Assignment. This Agreement may not be assigned by any Party except by

operation of law resulting from the merger of a Party into or with another corporate entity.

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

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

18.8 Foreign Access to Technology & Domestic Manufacturing.

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

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

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

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

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

SIGNATURES:

Recipient	**Government**
_____	_____

(b) (6)

Signature

(b) (6)

Printed Name

(b) (6)

Title

7/1/2020

Date

(b) (6)

Signature

(b) (6)

Printed Name

Agreements Officer

Title

Date