

10 USC 2373 AGREEMENT

BETWEEN

Ology Bioservices, Inc. (Awardee or Contractor)
13200 NW Nano Court
Alachua, FL 32615

And

NATICK CONTRACTING DIVISION (Government)
110 Thomas Johnson Dr.
Frederick, MD 21702

Effective Date: 21 Feb 2020

Agreement No.: W911QY-20-9-0003

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

Ology Bioservices, Inc.

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

Signature

(b) (6)

Printed Name

Senior VP, Government Contracts

Title

21 February 2020

Date

Government

(b) (6) (b) (6) 1033291600
2020.02.21 19:16:05 -05 00

Signature

(b) (6)

Printed Name

Agreements Officer

Title

21 Feb 2020

Date

ARTICLE 1. Scope.

A. This 10 U.S.C. § 2373 Agreement (the “Agreement”) is entered into between the Government and the Awardee on the Effective Date set forth above. For the avoidance of doubt, this Agreement is entered into pursuant to 10 U.S.C. § 2373 and is not a procurement contract governed by the Federal Acquisition Regulation (FAR), a grant, cooperative agreement, or 10 U.S.C. § 2371(b) other transaction agreement. The FAR and the Defense Federal Acquisition Regulation Supplement (DFARS) apply only as specifically referenced herein. This Agreement is not intended to be, nor will it be construed as, forming, by implication or otherwise, a partnership, a corporation, or other business organization. This Agreement is not subject to the Bayh-Dole Act, 35 U.S.C. §§ 200-212.

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

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

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

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

F. (b) (4)

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

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

ARTICLE 2. Term and Termination.

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

B. Termination for Convenience: The Government may terminate this Agreement for any or no reason by providing at least one hundred eighty (180) calendar days' prior written notice to the Awardee. The Government and Awardee will negotiate in good faith a reasonable and timely adjustment of all outstanding issues between the Parties as a result of termination by the Government for convenience, consistent with the terms of this Agreement. Termination of this Agreement will not impact ongoing projects which were awarded prior to the notice of termination under this Agreement.

C. Termination for Cause: If the Awardee materially fails to comply with the provisions of this Agreement, the Agreement Officer (AO), after issuance of a cure notice and failure of the Awardee to cure the defect within thirty (30) calendar days or the time allowed by the AO after Awardee's receipt of the cure notice, whichever is longer, may take one or more of the following actions as appropriate:

- (i) temporarily withhold payments pending correction of the deficiency,
- (ii) disallow all or part of the cost of the activity or action not in compliance,
- (iii) wholly or partly suspend or terminate this Agreement, including the termination of one or more SOWs issued under this Agreement,
- (iv) withhold further funding,
- (v) require Awardee to pay repurchase costs as defined in Article 2C1, Repurchase Against Contractors Account, or
- (vi) take any other legally available remedies.

1. Repurchase Against Contractors Account.

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

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

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

2. Termination for Cause Procedures.

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

Notwithstanding this Article 2.C, the Government's rights and Awardee 's obligations under this paragraph will cease to exist if the Government terminates this Agreement for any reason other than for Awardee 's failure to materially comply with the terms of this Agreement.

D. Survival: Except as noted in Article 2.C., in the event of Termination, all rights, obligations, and duties hereunder, which by their nature or by their express terms extend beyond the expiration or termination of this Agreement, including but not limited to warranties, indemnifications, intellectual property (including rights to and protection of Intellectual Property and Proprietary Information), and product support obligations shall survive the expiration or termination of this Agreement.

ARTICLE 3. Project Management.

A. Program Governance: The Awardee is responsible for the overall management of the project development program and related program decisions. The Government will have continuous involvement with the Awardee concerning SOW's directly associated with this Agreement. The Awardee shall provide access to project results in accordance with the Awardee's Project Timeline located in Appendix A.

B. Project Managers: The Awardee and the Government will each designate a Project Manager responsible for facilitating the communications, reporting, and meetings between the Parties. Each Party will also designate an alternate to the Project Manager, in case the primary Project Manager is unavailable. See Project Manager/Alternate Project Manager point of contact information for each respective party below:

Awardee Project Managers:

Primary Project Manager:	Alternate Project Manager:
(b) (6)	

Government Project Managers (GPM):

Primary Project Manager:	Alternate Project Manager:
(b) (6)	

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

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

ARTICLE 4. Agreement Administration.

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

Government Representatives:

Agreements Officer (AO)

(b) (6)

Agreement Specialists (AS)

Primary	Alternate
(b) (6)	(b) (6)

Awardee Representatives:

(b) (6)

ARTICLE 5. Performance Objectives and Changes.

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

B. Recommendations for Modifications: At any time during the term of this Agreement, progress or results may indicate that a change in the SOW would be beneficial to the project objectives. Recommendations for modifications, including justifications to support any changes to the SOW, will be documented in a letter and submitted by Awardee to the GPM with a copy to the AO. This letter will detail the technical, chronological and financial impact, if any, of the proposed modification to the project. Any resultant modification is subject to the mutual agreement of the Parties. The Government is not obligated to pay for additional or revised costs unless and until this

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

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

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

E. Amending the Agreement: The Government will be responsible for effecting all modifications to this Agreement, with the concurrence of the Awardee for modifications that are not minor or administrative. Administrative and material matters under this Agreement will be referred to the AO.

F. Modification Communications: No other communications, whether oral or in writing, that purport to change this Agreement are valid.

G. Government Property: If applicable, terms and conditions applicable to Government Property shall be incorporated through Appendix C.

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

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

ARTICLE 6. INSPECTION/ACCEPTANCE

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

employees and contractors of the FDA, may inspect the areas of premises of the Awardee or any subawardee that are specifically designated to the performance of the work under the applicable SOW. Inspections and testing will be requested and scheduled between the Government Project Manager (or its designee) and Awardee Project Manager. The Government shall perform inspections and tests in a manner that will not unduly delay the work, and during an agreeable time and date for both the Government and Awardee (subawardee). If the Government performs any required inspection or test on the premises of the Awardee or a subawardee, the Awardee shall furnish and shall require subawardees to furnish, at no increase in price, all reasonable facilities and assistance for the safe and convenient performance of these duties. Except as otherwise provided in the Agreement, the Government shall bear the expense of Government inspections or tests made at other than the Awardee's or subawardee's premises.

B. The Government shall inspect/accept or reject the work after completion/delivery, unless otherwise specified in the Agreement. Work is nonconforming when it is defective in material or workmanship or is otherwise not in conformity with Agreement requirements. The Government has the right to reject nonconforming work. Inspection/Acceptance of the deliverable(s) performed at Awardee's facility shall not exceed 120 days after completion. The Government waives the right to reject nonconforming work should it fail to notify the Awardee within the 120 days of delivery, unless otherwise specified in the applicable SOW. Acceptance of the work shall be conclusive. The Government shall notify the Awardee, and separately negotiate storage of a deliverable, if storage of the work is anticipated to exceed 120 days.

ARTICLE 7. Financial Matters

This is an expenditure-based agreement. The payments provided under this Agreement are intended to compensate the Awardee on a cost basis for performance under this Agreement. The Awardee shall provide its best efforts to complete a project based on the estimated cost.

A. Payment. Payments are based on amounts generated from the Awardee's financial or cost records. The Awardee shall be reimbursed for each element identified in the awarded cost proposal as set forth in Appendix B. The schedule is predicated upon the Government's fiscal year, which begins on October 1 of each calendar year, and ends on September 30 of the subsequent calendar year.

B. Obligation. Under no circumstances shall the Government's financial obligation exceed the amount obligated in this Agreement or by amendment to the Agreement. The Government may incrementally fund this agreement. The amount of Government funds obligated by this Agreement and available for payment is set forth in the Line of Accounting and Appropriation, or subsequent amendments providing incremental funding.

C. The Government is not obligated to provide payment to the Awardee for amounts in excess of the amount of obligated funds allotted by the Government.

D. The Government shall pay the Awardee, upon submission of proper invoices, the prices stipulated in this Agreement for work delivered or rendered and accepted, less any

deductions provided in this Agreement. Unless otherwise specified, payment shall be made upon acceptance of any portion of the work delivered or rendered for which a price is separately stated in the Agreement. Payments processed in WAWF and should be made within thirty (30) calendar days of receipt of a request for payment.

E. WIDE AREA WORKFLOW PAYMENT INSTRUCTIONS

(a) Definitions.

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

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

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

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

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

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

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

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

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

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

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

Routing Data Table*

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

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

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

(b) (6)

[Redacted]

(g) WAWF point of contact.

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

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

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

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

ARTICLE 8. Reserved

ARTICLE 9. Intellectual Property Rights

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

A. Background Intellectual Property and Materials. The Awardee and the Government each retain any intellectual property (IP) rights to their own materials, data, technology, information, documents, or know-how—or potential rights, such as issued patents, patent applications, invention disclosures, or other written documentation—that exist prior to execution of this Agreement or are developed outside the scope of this Agreement (“Background IP”). Additionally, no party to this Agreement will enter into an agreement with any manufacturer or other third party whereby the third party will obtain rights in Agreement Inventions or Study Data, as those terms are defined in this Agreement, absent the mutual consent of the parties to the awarded contract.

B. Definitions. For purposes of this agreement, an “Agreement Invention” is any invention, regardless of whether it is not patentable, or is patentable under U.S. patent law that is conceived or first reduced to practice under this Agreement.

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

D. Patent indemnity. The Awardee shall indemnify the Government and its officers, employees and agents against liability, including costs, for actual or alleged direct or contributory infringement of, or inducement to infringe, any United States or foreign patent, trademark or copyright, arising out of this Agreement, provided the Awardee is notified of such claims and proceedings as soon as practicable by the Government of the suit or action alleging such infringement and shall have been given such opportunity as is

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

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

E. Patent Prosecution. Awardee agrees to take responsibility for the preparation, filing, prosecution, and maintenance of any and all patents and patent applications listed as Awardee Background IP that are relevant to work performed under this Agreement. Awardee shall keep the Government reasonably advised on the status of Awardee Background IP by providing an annual report on the status of Awardee Background IP. Prior to acting on a decision by Awardee to abandon or not file in any country a patent or patent application covering an Agreement Invention, which is defined below, Awardee shall so inform the Government in a timely manner to allow Awardee to thoughtfully consider the Government's comments regarding such a proposed decision. Nothing in this Article 10 shall restrict the Government in its preparation, filing, prosecution and maintenance of a patent or patent application covering an Agreement Invention.

F. Patent Enforcement. Awardee will have the first option to enforce any patent rights covering an Agreement Invention owned jointly by the Parties or solely by Awardee, at Awardee's expense. If Awardee chooses not to exercise this option, the Government may enforce patent rights covering a joint Agreement Invention only with Awardee's prior written approval.

G. Ownership. Ownership of any invention, regardless of whether it is not patentable, or is patentable under U.S. patent law that is conceived or first reduced to practice under this Agreement (Agreement Invention) will follow inventorship in accordance with U.S. patent law. The Bayh-Dole Act, 35 U.S.C. §§ 200-212 does not apply to this Agreement and, as such, title to Agreement Inventions will accrue to the inventor or inventor-organization. The Parties represent and warrant that each inventor will assign his or her rights in any such inventions to his or her employing organization. If either an Awardee employee or a Government employee makes a sole Agreement Invention, the entire rights to that Agreement Invention will be respectively assigned to the Awardee or the Government. If an Awardee employee and a Government employee jointly make an Agreement Invention, it will be owned jointly by the Awardee and the Government. Ownership of Agreement Inventions made in whole or in part with subawardee employees, including employees of other components of the Government, will be determined solely pursuant to an agreement between the Awardee and the applicable subawardee.

H. Patent Applications. The Parties will respectively have the option to file a patent application claiming any Agreement Invention made solely by their respective employees. The Parties will consult with each other regarding the options for filing a patent application claiming a joint Agreement Invention. Within thirty (30) calendar days of being notified of the discovery of an Agreement Invention or filing a patent application

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

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

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

ARTICLE 10. Data Rights.

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

A. For purposes of this Agreement, "Study Data" is all data generated in connection with the performance of the studies under this Agreement. Study Data shall be owned by the Awardee. The U.S. Government shall have the right to use, modify, reproduce, release, perform, display, or disclose data first produced in the performance of this Agreement within the Government and otherwise for "Unlimited Rights," as this term is defined in DFARS 252.227-7013(a)(16). The Government may, under a separate agreement or by modification to this Agreement, obtain any rights to use or disclose the Awardee's

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

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

B. The Awardee agrees to retain and maintain in good condition until five (5) years after completion or termination of this Agreement, all Study Data generated under this Agreement. In the event of exercise of the Government's rights as potentially granted under paragraph 2.C, the Awardee agrees to deliver at no additional cost to the Government, all Study Data, in Awardee's possession and developed under this Agreement, necessary to deliver the supplies identified on the particular SOW within sixty (60) calendar days from the date of the written request.

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

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

Any rights that the Awardee or the Government may have in Study Data delivered under this Agreement, whether arising under this Agreement or otherwise, will not be affected by Awardee's failure to mark data pursuant to this Article.

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

ARTICLE 11. Regulatory Rights.

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

This Agreement may include research with one or more investigational drug, biologic or medical device that is regulated by the U.S. Food and Drug Administration (FDA) and requires FDA pre-market approval or clearance before commercial marketing may begin. Subject to further negotiation between the parties and set forth in the SOW, the Contractor may serve as the

Sponsor of the Regulatory Application (an Investigational New Drug Application (IND), Investigational Device Exemption (IDE), New Drug Application (NDA), Biologics License Application (BLA), Premarket Approval Application (PMA), or 510(k) Pre-Market Notification Filing (510(k)) or another regulatory filing submitted to FDA) that controls research under this agreement. The Sponsor of the Regulatory Application to FDA (as the terms “sponsor” and “applicant” are defined or used in at 21 CFR §§3.2(c), 312.5, 600.3(t), 812.2(b), 812 Subpart C, or 814.20) has certain standing before the FDA that entitles it to exclusive communications related to the Regulatory Application.

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

- a. The Contractor shall provide to the Government all data, including top-line summaries and key conclusions from all studies, supporting the regulatory filing and commercial approval to the extent that such data, summaries, and conclusions are funded under this Agreement. In addition, the Contractor will offer the Government the opportunity to review and provide comments on a final draft of regulatory submissions which include data funded under this Agreement. The Government will review any such submissions promptly upon receipt. The Contractor shall reasonably consider any comments provided by the Government, and prior to submission shall provide notification to the Government of any additional edits or revisions. The Contractor shall keep the Government reasonably apprised of planned FDA meetings and post-meeting outcomes relating to activities funded under this Agreement.
- b. Communications. The Contractor shall provide the Government with all communications and summaries thereof, both formal and informal, to or from FDA regarding the regulatory submissions subject to this Agreement and ensure that the Government representatives are invited to participate in any formal Sponsor meetings with the FDA. The Contractor shall use its best efforts to ensure that the Government representatives are invited to participate in any informal Sponsor meetings with the FDA so long as the Contractor has 48 hour advance notice of such Sponsor meeting from the FDA prior to the scheduled meeting time.
- c. Non-compliance with section (b) may result in termination of the agreement.
- d. Product Development Failure. Certain product development failures may trigger certain remedies in Section “e.” below for the Government advanced developer funding the development of the work contemplated in the applicable SOW. This remedy is not available to the Government for any cause outside of the following:
 - (i) if this agreement is terminated for nonperformance; or
 - (ii) the Contractor gives notice, required to be submitted to the Government no later than 30 business days, of any formal management decision to terminate this product development effort pre-market or to file for Federal bankruptcy protection.
- e. If any of the product development failures listed in section “d” occur, the Contractor, upon the request of the Government:
 - (i) shall transfer possession, ownership and sponsorship or holdership of any Regulatory Application (including any associated expedited review designation, priority review voucher, or marketing exclusivity eligibility or award), regulatory correspondence, and supporting regulatory information related to the Technology to the Government or its designee;

- (ii) shall inform FDA of the transfer of sponsorship or holdership of the Regulatory Application transferred under section (e)(i) above; and
 - (iii) shall negotiate in good faith a non-exclusive license, at customary industry rates and under reasonable terms and conditions, to any patent, copyright or other intellectual property owned or controlled by the Contractor, developed prior to or outside the scope of this agreement, or any technical data that is necessary for the Government to pursue commercialization of this technology with a third party for sale to the Government or otherwise.
- f. This clause will survive the acquisition or merger of the Contractor by or with a third party. This clause will also be included in any subcontracts/sub agreements relating to the development of the Technology. This clause will survive the expiration of this agreement.

ARTICLE 12. Foreign Access to Data.

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

ARTICLE 13. Scientific Publications and Press Releases.

A. The Parties shall jointly agree on a publication plan for the data derived from studies executed under this Agreement (such data to be considered New Data). This publication plan will identify key New Data to be disclosed or presented and the target date for finalizing any related scientific abstract or manuscript. As part of its Monthly Progress Reports, the Awardee will share the publication plan with the Government.

B. The Parties will jointly develop each abstract or manuscript and agree on the authorship and the content of the final draft to be submitted; provided that authorship for each abstract and manuscript will be determined based on whether a particular individual made a significant contribution to the conceptualization, design, execution, or interpretation of a research study, as authorship is defined in the fifth edition of the Guidelines and Policies for the Conduct of Research in the Intramural Research Program at NIH, available at: https://oir.nih.gov/sites/default/files/uploads/sourcebook/documents/ethical_conduct/guidelines-conduct_research.pdf.

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

D. The Parties will jointly agree on whether to issue one or more press releases related to the resulting New Data. If all Parties agree that one or both Parties will issue a press release, each Party will also have the right to review and agree on the content in advance of its publication. Other parties, if any, contributing to the studies, will have review rights and will be appropriately accredited in the press release. For data generated in studies

executed by Awardee outside the scope of this Agreement, the Awardee, at its sole discretion, may issue a press release related to such data.

ARTICLE 14. Miscellaneous Clauses.

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

B. Patent Infringement. Each Party will advise the other Party promptly and in reasonable written detail, of each claim or lawsuit of patent infringement based on the performance of this Agreement. When requested by either Party, all evidence and information in possession of the Party pertaining to such claim or lawsuit will be provided to the other at no cost to the requesting Party.

C. Limitation of Liability. In no event will either Party be liable to the other Party or any third party claiming through such Party for any indirect, incidental, consequential or punitive damages, or claims for lost profits, arising under or relating to this Agreement, whether based in contract, tort or otherwise, even if the other Party has been advised of the possibility of such damages.

D. Disclosure of Information. Subject to Articles 10 and 11, the Awardee shall not release to anyone outside the Awardee's organization any unclassified information, regardless of medium (e.g., film, tape, document), pertaining to any part of this Agreement or any program related to this Agreement, unless (i) the Agreements Officer has given prior written approval or (ii) the information is otherwise in the public domain before the date of release.

E. Force Majeure. Neither Party will be liable to the other Party for failure or delay in performing its obligations hereunder if such failure or delay arises from circumstances beyond the control and without the fault or negligence of the Party (a Force Majeure event). Examples of such circumstances are: authorized acts of the government in either its sovereign or contractual capacity, war, insurrection, freight embargos, fire, flood, or strikes. The Party asserting Force Majeure as an excuse must take reasonable steps to minimize delay or damages caused by unforeseeable events.

F. Severability. If any provision of this Agreement, or the application of any such provision to any person or set of circumstances, is determined to be invalid, unlawful, void or unenforceable to any extent, the remainder of this Agreement, and the application of such provision to persons or circumstances other than those as to which it is determined to be invalid, unlawful, void or unenforceable, will not be impaired or otherwise affected and will continue to be valid and enforceable to the fullest extent permitted by law.

G. Priority Access.

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

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

2) Reserved.

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

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

J. (b) (4)



K. Choice of Law. This Agreement and the resolution of disputes hereunder will be governed, construed, and interpreted by the statutes, regulations, and/or legal precedent applicable to the Government of the United States of America. Unless explicitly stated, the Parties do not intend that this Agreement be subject to the Federal Acquisition Regulation either directly or indirectly or by operation of law. When a specific FAR requirement is incorporated by reference in this Agreement, the text of the clause alone will apply without application or incorporation of other provisions of these regulations.

L. Order of Precedence. In the event of a conflict between the terms of this Agreement and the attachments incorporated herein, the conflict shall be resolved by giving

precedence in descending order as follows: (i) each SOW as included in Appendix A, (ii) the Articles of this Agreement, and (iii) other Appendices to the Agreement.

(b) (4)

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Appendix B

Project Schedule Payment Schedule

The Government shall pay the Contractor, upon the submission of proper invoices or vouchers Expenditures shall be submitted based on the awarded budget. Federal funds are to be used only for costs that a reasonable and prudent person would incur in carrying out the work. The Awardee must maintain a financial system capable of identifying costs applicable to this Agreement, compliant with Cost Principles (48 CFR Part 31). An invoice will be submitted through Wide Area Work Flow (WAWF) in accordance with agreement requirements. Final payment of the Agreement shall be determined upon mutual agreement and settlement of any outstanding indirect costs.

The Awardee shall proceed with the performance in accordance with the terms and conditions of this Agreement and its Appendices. However, the Government may require the Awardee to cease performance at any time prior to the commencement of any milestone or task. Such notice to cease performance must be from the AO and be in writing, of which email is an acceptable form.

Appendix C Government Property

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

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

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

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

The Awardee shall have, initiate and maintain a system of internal controls to manage, control, use, preserve, protect, repair, account for and maintain Government Property in its possession and shall initiate and maintain the processes, systems, procedures, records required control and maintain accountability of Government Property. The Awardee shall include this clause in all subcontracts under which Government Property comes into the possession of any subawardee. Unless otherwise provided for in this Agreement or approved by the AO, the Awardee shall not: (i) use Government Property for any purpose other than to fulfill the requirements of this Agreement, or (ii) alter the Government Property.

The Awardee shall establish and implement property management plans, systems, and procedures regarding its acquisition of Government Property, its receipt of Government Property, in addition to, the status, dates furnished or acquired, identification, quantity, cost, marking, date placed in service, location, inventory and disposition of Government Property, to include a reporting process for all discrepancies, loss of Government Property, physical

inventory results, audits and self-assessments, corrective actions, and other property related reports as directed by the AO.

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

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