EX-10.1 2 a200622dodnatickotaagr.htm EXHIBIT 10.1

Exhibit 10.1

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT HAVE BEEN OMITTED AND REPLACED WITH "[***]". SUCH IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT (I) IS NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF DISCLOSED.

OTHER TRANSACTION AUTHORITY FOR PROTOTYPE AGREEMENT

BETWEEN

Inovio Pharmaceuticals, Inc. (Awardee) 660 W Germantown Pike Ste 110
Plymouth Meeting, PA, 19462-1111
And
NATICK CONTRACTING DIVISION (Government)
110 Thomas Johnson Dr. Frederick, MD 21702

Effective Date: 22 June 2020 Agreement No.: [***]

Total Amount of the Agreement: $[***]

Awardee	Government
/s/ J. Joseph Kim	/s/ Lawrence Mize
Signature	Signature
J. Joseph Kim	Lawrence Mize
Printed Name	Printed Name
CEO	Agreement Officer
Title	Title
6/20/2020	6/20/2020
Date	Date

[1] Appendices and schedules have been omitted pursuant to Item 601(a)(5) of Regulation S-K and will be furnished on a supplemental basis to the Securities and Exchange Commission upon request.

This Other Transaction Authority for Prototype Agreement is entered into between the United States of America, hereinafter called the “Government”, pursuant to and under U.S. Federal law, and Inovio Pharmaceuticals, Inc. a small business, non-traditional defense contractor, hereinafter called the “Awardee”. The United States of America and Awardee are sometimes referred to herein individually as a “Party” and collectively as the “Parties.”

WHEREAS, the Awardee is eligible for an Other Transaction Authority for Prototype Agreement in accordance with 10 USC § 2371b(d)(1)(A) as amended by the National Defense Authorization Act for Fiscal Year 2018 as they are non-traditional defense contractor;

WHEREAS, in accordance with 10 U.S.C. 2371b, The Department of Defense currently has authority to award “other transactions” (OTs) in certain circumstances for prototype projects that are directly relevant to enhancing the mission effectiveness of military personnel and the supporting platforms, systems, components, or materials proposed to be acquired or developed by the Department of Defense, or to improvement of platforms, systems, components, or materials in use by the Armed Forces. To the maximum extent practicable, competitive procedures shall be used when entering into agreements to carry out projects under subsection (a);

WHEREAS, the parties are developing a prototype only for use with Inovio's approved products and under Inovio’s regulatory filings, whereby such protoype can generally be described as a proof of concept, model, reverse engineering to address obsolescence, pilot, novel application of commercial technologies for defense purposes, agile development activity, creation, design, development, demonstration of technical or operational utility, or combinations of the foregoing;

WHEREAS, this Agreement meets the criteria for a prototype project; NOW THEREFORE, the Parties have

agreed as follows:

ARTICLE 1. Scope.

This Other Transaction Authority for Prototypes 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.
§ 2371b and is not a procurement contract governed by the Federal Acquisition Regulation (FAR), a grant, or cooperative 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- 12.

B. The Parties agree that the sole purpose of this Agreement is for the development of an FDA approved next generation electroporation device and array for DNA Vaccine delivery of INO-4800 against COVID-19, with demonstrated capability to be produced at a large scale, as well as full automation for production of the device arrays, (hereinafter referred to as the "Prototype Project"). The Awardee shall develop the Prototype as described in the Awardee’s Statement of Work (SOW), which is incorporated herein and attached hereto as Appendix A. For purposes of clarity, this Agreement does not contemplate Government use of the Prototype while it is an investigational device. Any subsequent Government purchase of the Prototype or the FDA-cleared device, including a follow-on contracting action under 10 USC 2371b(f), shall specify the terms of Government use, which shall be conducted

under Inovio's regulatory filings or under the terms of the FDA's clearance and consistent with the product labeling. No further use is permitted without Inovio's explicit prior written consent, whereby any such permitted use shall be negotiated by the parties and subject to a future agreement.

C. The prototype will be deemed successful where the Awardee's efforts meet the key technical requirements and are sufficient to meet an FDA compliant final report(s) that supports the completion of a human clinical trial(s). Follow on production pursuant to 10 USC 2371b is anticipated to be [***], which the Parties agree to negotiate such terms in good faith pursuant to a separate agreement.

ARTICLE 2. Term and Termination.

A. Term: The Term of this Agreement commences upon the Effective Date and extends through final payment. This Agreement is anticipated to end [***], subject to completion of the project(s). A transaction for a prototype project is complete upon the written determination of the appropriate official for the matter in question that efforts conducted under a Prototype OT: (1) met the key technical goals of a project, or (2) accomplished a particularly favorable or unexpected result that justifies the completion of the prototype.

B. Termination for Convenience: The Government may terminate this Agreement for any or no reason by providing at least thirty (30) 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.

C. Termination for Cause: If the Awardee materially fails to comply with the provisions of this Agreement, the Other Transaction Agreement Officer (OTAO), after issuance of a cure notice and failure of the Awardee to cure the defect within ten (10) business days or the time allowed by the OTAO 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,
iv. withhold further funding,
v. require Awardee to pay repurchase costs as defined in Article 2C1, Repurchase Against vi. Contractors Account, or
vi. take any other legally available remedies.

1. Repurchase Against Contractors Account.
a. When the Prototype is still required after termination, the AO shall repurchase the same or a similar prototype 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.
If repurchase is made at a price over the price of the Prototype 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.

b. If this Agreement is terminated for Cause, Awardee will grant the Government a non- exclusive, paid up, license to the Awardee and subawardee patents and documentation necessary for the purpose of developing the Prototype solely for use with the INO-4800 product for COVID-19 and shall only be conducted under Inovio's regulatory filings and solely for the pandemic period as applicable in the United States. No further use is permitted without Inovio's explicit prior written consent, whereby any such permitted use shall be negotiated by the parties and subject to a future agreement. The Awardee shall provide the Government or its designee with a non-exclusive, paid up, license to any patent, copyright, technical data or regulatory information held by the Awardee that relates to the technology to permit the Government to pursue commercialization of the technology with a third party solely for use with the INO-4800 product for COVID-19 and shall only be conducted under Inovio's regulatory filings and solely for the pandemic period as applicable in the United States. No further use is permitted without Inovio's explicit prior written consent, whereby any such permitted use shall be negotiated by the
parties and subject to a future agreement, 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: 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. 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:
[***]	
[***]	
[***]	

Government Project Managers (GPM)

Primary Project Manager:	Alternate Project Manager:
[***]	[***]
[***]	[***]
[***]	[***]

C. Key Personnel: The Awardee's organization shall be established with authority to effectively develop the Prototype. This organization shall become effective upon execution of this Agreement and its integrity shall be maintained until completion or acceptance of the effort by the Government. The key personnel listed in Appendix C 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 OTAO. 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. Subaward Approval: Modifications to subawards and/or new subcontracts under this Agreement after the Effective Date that could reasonably impact the technical approach proposed and accepted by the Government require the approval of the OTAO prior to being executed.

E. The OTAO has assigned an Agreements Officer’s Representative (AOR) for this agreement. The Awardee will receive a copy of the written designation outlining the roles and responsibilities of the AOR and specifying the extent of the AOR’s authority to act on behalf of the OTAO. The AOR is not authorized to make any commitments or changes that will affect price, quality, quantity, delivery, or any other term or

condition of the contract.

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 OTAO be effective or binding upon the Government. All such actions must be formalized by a proper contractual document executed by the OTAO.

Government Representatives:
Other Transaction Agreements Officer [***]
[***]
[***]
[***]
[***]
[***]
[***]
[***]

Other Transaction Agreement Specialist [***]
[***]
[***]
[***]
[***]
[***]
[***]
[***]

Agreements Officer’s Representative [***]
[***]
[***]
[***]
[***]
[***]
[***]
[***]

Awardee Representatives:
[***]
[***]
[***]

[***]
[***]

[***]
[***]
[***]
[***]
[***]

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 to achieve the objective.

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 OTAO. 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 OTAO 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 OTAO will be responsible for the review and verification of any recommendations to revise or otherwise modify the Agreement, the SOW, the milestone payments, or other proposed changes to the terms and conditions of this Agreement.

D. Minor Modifications: The Government may make minor or administrative Agreement modifications unilaterally (e.g., changes in the paying office or appropriation data, changes to Awardee personnel proposed by Awardee, 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 OTAO.

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 D.

E. 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 OTAO. The OTAO will review the matter and render a decision in writing within sixty (60) calendar days. Thereafter, 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 by mutual consent to explore and establish and Alternate Disputes Resolution procedure to resolve this dispute. The Awardee shall proceed diligently with performance under this agreement pending resolution of the dispute.

ARTICLE 6. Inspection/Acceptance

A. Inspection: The Government has the right to inspect and test all work called for by this Agreement, to the extent practicable at all places and times, including the period of performance, and in any event before acceptance. The Government may also inspect the premises of the Awardee or any subawardee engaged in performance. The Government shall perform inspections and tests in a manner that will not unduly delay the work. If the Government performs any 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 as promptly as practicable after completion/delivery, unless otherwise specified in the Agreement. Government failure to inspect and accept or reject the work shall not relieve the Awardee from responsibility, nor impose liability on the Government, for nonconforming work. Work is nonconforming when it is defective in material or workmanship or is otherwise not in conformity with Agreement requirements. The Government has the right to reject nonconforming work. Inspection/Acceptance of the Prototype performed should not exceed 90 days after completion

ARTICLE 7. Financial Matters

A. This Agreement is an expenditure type Other Transaction Authority 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 prototype project based on the estimated cost. Payments are based on amounts generated from the Awardee's financial or cost records.

B. 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, executed and accomplished in accordance with the performance schedule set forth in Appendix B. The schedule is predicated upon the Government's fiscal year, which begins on October 1 of each year, and ends on September 30 of the subsequent calendar year.

C. Obligation. Under no circumstances shall the Government's financial obligation exceed the amount obligated in this Agreement or by amendment to the Agreement. The amount of Government funds obligated by this Agreement and available for payment is set forth in the supplemental PD2 version of the agreement, and any subsequent modifications. The Government may incrementally fund this agreement.

D. 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.

E. The Government shall pay the Awardee, upon submission of proper invoices, the costs 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 will be made within thirty (30) calendar days of receipt of a request for payment.

F. Prior written approval by the OTAO, or the AOR, is required for all travel directly and identifiably funded by the Government under this agreement. The Awardee shall present to the OTAO or AOR, an itinerary for each planned trip, showing the name of the traveler, purpose of the trip, origin/destination, dates of travel, and estimated cost broken down by line item as far in advanced of the proposed travel as possible, but no less than two weeks before travel is planned to commence. In the event that emergency travel is required (e.g. in the event of an outbreak) that would make two weeks' notice impractical, travel requests may be submitted to the Government for an expedited

review. Emergency travel requests shall be labelled as such and shall include a brief summary of the emergency situation and rationale for expedited review.

G. WIDE AREA WORKFLOW PAYMENT INSTRUCTIONS (MAY 2013)

1. 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.

2. 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.

3. 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.

4. 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/.

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

6. WAWF payment instructions. The Awardee must use the following information when submitting payment requests and receiving reports in WAWF for this Agreement:

i. Document type. The Awardee shall use the following document type: Voucher

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

iii. 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

Field Name in WAWF	***Data to be entered in WAWF***
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

7. 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, costs, fee (if applicable), and all relevant back-up documentation in support of each payment request.

8. 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.

[***]
[***]
[***]

[***]
[***]

[***] [***]

[***] [***]

9. WAWF point of contact.

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

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

(End of Clause)

H. 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. Report and Data Requirements

A. Weekly Teleconferences and Communication

Awardee shall conduct weekly teleconferences with the Government throughout the performance of the Agreement to discuss tasks accomplished and direction for the upcoming tasks. The Government anticipates reducing the teleconferences once enrollment executes and again after completion of the trial. Awardee shall provide agendas and read-ahead material as required two days prior to the meetings and shall provide minutes of each meeting to the Government. Awardee shall include key subcontractors as attendees at these teleconferences when applicable. The Awardee shall provide meeting minutes within [***] after each formal scheduled meeting/teleconference conducted with JPEO EB.

B. Quarterly Progress Reports

The Awardee shall submit a Quarterly Progress report within [***] after the end of each quarter of performance. The Quarterly Progress report shall contain the technical progress made during the previous quarter and the updated resource loaded Integrated Master Schedule (IMS) in Microsoft Project format. The schedule update shall include the explanation for any changes in the schedule, and drivers for the changes, as applicable. The report should also address any concerns that would impact the performance, schedule, or cost planned for the effort. The Awardee shall report risk matrix

format to include risk mitigation strategies. Note: Any identified changes require formal notification to the OTAO in accordance with the Agreement provisions.

In addition, the Quarterly Progress Report shall contain regular status updates of all Intellectual Property (IP) license(s) related to the effort to ensure that all license(s) are in good standing as the project progresses. In the event of any change in IP license(s) status or potentially imminent change in status, the Awardee shall immediately contact the OTA and GPM in writing.

The Government will have [***] to respond to the report with any comments and the Awardee will have [***] to revise the deliverable or respond to those comments.

C. Quarterly Financial Status Report

The Awardee shall submit a Quarterly Financial Status Report no later than [***] after the end of each quarter of performance. The Government will have [***] to respond to the report with any comments and the Awardee will have [***] to revise the deliverable or respond to those comments. Reports will cover work performed every three (3) months for the duration of the Period of Performance (PoP).

In addition, the Quarterly Financial Status Report shall include quarterly expenditure forecasts with both the quarterly planned accrual and the cumulative total. Expenditure forecast submissions shall include analysis of the cost drivers for Estimate to Complete changes, if any, from the previous projection. The Awardee shall provide all submissions in Excel format, including all formulas.

D. Expenditure Forecasts

The Awardee shall submit the first expenditure forecast within thirty (30) calendar days after receiving the project award. An updated forecast shall be submitted within [***] of any project modifications that modify the PoP or the cost of the prototype. Expenditure forecast submissions shall include analysis of the cost drivers for Estimate to Complete changes, if any, from the previous projection. The Awardee shall provide all submissions in Excel format, including all formulas.

E. Final report

A Final Report shall be prepared at the end of the effort by the Awardee. The Final Report shall narrate a complete summary of the project execution and associated results obtained. The narration will include outstanding problems and their potential solutions, problems solved during the course of the agreement, and the solutions to the solved problems. The Final Report shall demonstrate how the prototype was developed and advanced.

The Awardee shall submit a Draft Final Report by the [***] following the end of the project. The Government shall provide comments to the Awardee by the [***] following receipt of the Awardee's Draft Final Report. The Awardee shall submit the Final Report on the [***] after receipt.

F. Ad Hoc Meetings

In addition to the monthly meetings and written quarterly program updates, additional ad hoc meetings to address specific issues or to convey time- sensitive updates or scientific data related to the program will be held.

G. Patents - Reporting of Subject Inventions
For purposes of this paragraph, "Subject Invention" is defined as any invention, discovery, or improvement of the Awardee, whether or not patentable, that are conceived of or first actually reduced to practice in the performance of work under this Agreement. The Awardee shall report any OTA Inventions in accordance with the terms and conditions of this Other Transaction Agreement (OTA).

H. All documentation submitted to the government must have quality oversight from an independent quality group not reporting to the executing management group (for example; clinical trials group, data management group, etc)
8. Miscellaneous Data Submissions

I. If applicable, the Awardee must submit to the Government all Point Papers, Briefings, Technical Performance Plans (TPP), Program Development Plans (PDP), Regulatory Strategy, Technology Transfer Report and Gap Analysis, Formulation Development, Feasibility and Optimization Reports, United States Army Medical Research and Material Command Animal Care and Use Review Office (USAMRMC ACURO) Approvals, Human Resources Operations Branch (HROB) Approvals, Technical Presentations and Publications, and any formal technical reports that have been prepared for eventual submission to FDA or other regulatory agencies. Examples include the following reports related to: pharmaceutical development, manufacturing development, manufacturing validation, completed batch records, certificates of analysis, analytical development and validation, drug substance and product stability, nonclinical testing, and clinical testing. Examples include clinical performance and clinical quality documentation.

J. Work Breakdown Structure
Three-level WBS with costs and schedule (top level is program, level two (2) is phase, level three (3) are major tasks). For WBS level two (2), show breakdown for labor, material, and other indirect costs.

WBS shall be updated annually or [***] after a Statement of Work modification. Government review/approval is [***] after receipt of first submittal. Provide changes to draft within [***] of such request. Provide final document within [***]

after approval of changes is received.

K.Integrated Master Schedule
The Awardee shall provide within [***] after project award an IMS in Microsoft Project format. Any updates to the IMS shall be included in the monthly progress reports.

Submission shall be [***] after the end of each month of performance. The Government will have [***] to respond to the report with any comments and the performer will have [***] to revise the deliverable or respond to those comments.

L.Incident Report.

The Awardee shall report any incident to the Government that could result in more than a one month delay in schedule from the most recent IMS critical path delivered to the Government. Telephonically contact the GPM within one day of incident. A written summary report shall be submitted within [***] of an incident, to include, what happened, what was the impact, if there are any available corrective actions and a time line for when the corrective actions would be in place.

M.Quality Agreement.

The Awardee shall submit a quality agreement within 90 days of award for Government review. Upon acceptance the agreement is to be executed by both parties. This document must flow down to all subawards.

ARTICLE 9. Most Favored Customer

A. For a period of six (6) years from the Effective Date, Awardee agrees that it shall not offer, sell or otherwise provide the production model of the Prototype to any entity at a price lower than that offered to the DoD. In the event that Awardee sells the production model of the Prototype at a lower unit price than that price sold to the DoD, Awardee shall immediately notify the OTAO in writing of the lower price. For prior purchases, the Awardee shall reimburse the DoD, the difference between the lower price sold to the other customer(s) and the price sold to the DoD multiplied by the number of items sold. Such reimbursement shall occur within [***] of the Awardee discovering that the lower price was given to another customer. Notwithstanding the foregoing, the parties may agree to apply the difference in price paid by the other customer(s) and DoD into additional quantities required by the DoD.

B. If Awardee develops a like product (commercialized version or derivative of the production model of the Prototype) with similar capability and intended application, but at a lower unit price ("Like Product") regardless of quantity, Awardee shall make the DoD aware of that similar product and the technical and price differences between that product and

the Prototype. Such notification shall be made to the OTAO in writing, of which email is an acceptable form, within [***] of such offering. Awardee agrees that no entity shall receive a lower price for any Like Product than the DoD for like purchase quantities..

ARTICLE 10. Confidential Information

(i) Definitions

(1) "Disclosing Party" means the Government or the Awardee who discloses Confidential Information as contemplated by the subsequent Paragraphs.
(2) "Receiving Party" means Government or the Awardee who receives Confidential Information disclosed by a Disclosing Party.

(3) "Confidential Information" means information and materials of a Disclosing Party which are designated as confidential or as a Trade Secret in writing by such Disclosing Party, whether by letter or by use of an appropriate stamp or legend, prior to or at the same time any such information or materials are disclosed by such Disclosing Party to the Receiving Party. Notwithstanding the foregoing, materials and other information which are orally, visually, or electronically disclosed by a Disclosing Party, or are disclosed in writing without an appropriate letter, stamp, or legend, shall constitute Confidential Information or a Trade Secret (as defined below) if such Disclosing Party, within thirty (30) calendar days after such disclosure, delivers to the Receiving Party a written document or documents describing the material or information and indicating that it is confidential or a Trade Secret, provided that any disclosure of information by the Receiving Party prior to receipt of such notice shall not constitute a breach by the Receiving Party of its obligations under this Paragraph. "Confidential Information" includes any information and materials considered a Trade Secret by the Awardee. "Trade Secret" means all forms and types of financial, business, scientific, technical, economic, or engineering or otherwise proprietary information, including, but not limited to, patterns, plans, compilations, program devices, formulas, designs, prototypes, methods, techniques, processes, procedures, programs, or codes, whether tangible or intangible, and whether or how stored, compiled, or memorialized physically, electronically, graphically, photographically, or in writing if –

(a) The Disclosing Party thereof has taken reasonable measures to keep such information secret; and

(b) The information derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable through proper means by, the public.

B. Exchange of Information: The Government shall not be obligated to transfer Confidential Information independently developed by or on behalf of the Government absent an express written agreement between the Parties involved in the exchange providing the terms and conditions for such disclosure.

C. Authorized Disclosure: The Receiving Party agrees, to the extent permitted by law, that Confidential Information shall remain the property of the Disclosing Party (no one shall disclose unless they have the right to do so), and that, unless otherwise agreed to by the Disclosing Party, Confidential Information shall not be disclosed, divulged, or otherwise communicated by it to third parties or used by it for any purposes other than in connection with specified project efforts and the licenses granted in Article 11, Intellectual Property Rights, and Article 12, Data Rights, provided that the duty to protect such “Confidential Information” and “Trade Secrets” shall not extend to materials or information that:

(a) Are received or become available without restriction to the Receiving Party under a proper, separate agreement,

(b) Are not identified with a suitable notice or legend per Article 12 entitled "Confidential Information" herein,

(c) Are lawfully in possession of the Receiving Party without such restriction to the Receiving Party at the time of disclosure thereof as demonstrated by prior written records,

(d) Are or later become part of the public domain through no fault of the Receiving Party,

(e) Are received by the Receiving Party from a third party having no obligation of confidentiality to the Disclosing Party that made the disclosure,

(f) Are developed independently by the Receiving Party without use of Confidential Information as evidenced by written records,

(g) Are required by law or regulation to be disclosed; provided, however, that the Receiving Party has provided written notice to the Disclosing Party promptly so as to enable such Disclosing Party to seek a protective order or otherwise prevent disclosure of such information.

D. Return of Proprietary Information: Upon the request of the Disclosing Party, the Receiving Party shall promptly return all copies and other tangible manifestations of the Confidential Information disclosed. As used

in this section, tangible manifestations include human readable media as well as magnetic and digital storage media.

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

F. The Government shall flow down the requirements of this Article 10 to their respective personnel, member entities, agents, and Awardees (including employees) at all levels, receiving such Confidential Information under this Agreement..

ARTICLE 11. Intellectual Property Rights

A. Background IP 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 the Agreement will enter into an agreement with any contract manufacturer or other third party whereby the third party will obtain rights in OTA Inventions or Study Data, as those terms are defined in this Agreement, absent the mutual consent of the parties to the awarded contract, however any party having an existing agreement with Inovio shall not be subject to this requirement.

B. Awardee’s Background IP. Awardee warrants that it has filed patent application(s) or is the assignee of issued patent(s) directed to a device previously provided to the Government and hereby incorporated as Attachment 1 which contain claims that are related to research contemplated under this Agreement. No license(s) to any patent applications or issued patents shall be granted under this Agreement to the Government, and the application(s) and any continuing applications (except for continuing applications pursuant to this agreement) identified to the Government are specifically excluded from the definitions of "OTA Invention" contained in this Agreement: Background

C. 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 reasonably notified of such claims and proceedings.

D. 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 the 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 OTA 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 shall restrict the Government in its preparation, filing, prosecution and maintenance of a patent or patent application covering an OTA Invention.

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

F. 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 ("OTA 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 inventions will belong to the inventor or via assignment of ownership to the inventor-organization. The Parties represent and warrant that each inventor is obligated to assign and 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 OTA Invention, the entire rights to that OTA Invention will be respectively assigned to the Awardee or the Government. If an Awardee employee and a Government employee jointly make an OTA invention, it will be owned jointly by the Awardee and the Government. Ownership of inventions made in whole or in part with subawardee or collaborator employees, including employees of other components of the Government, will be determined solely pursuant to an agreement between the Awardee and the applicable subawardee or collaborator.

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

H. Licenses. Upon the Awardee's request, the Government agrees to enter into good faith negotiations with the Awardee regarding the Awardee's receipt of a nonexclusive commercialization license covering the Government's interest in any OTA Invention made in whole by a Government employee. Any OTA Invention made solely by an Awardee employee is subject to a nonexclusive, nontransferable, irrevocable, paid- up license for the Government to practice and have practiced the OTA Invention with "Unlimited rights," as this term is defined in DFARS 252.227-7013a)(16), as if this regulation were applicable to inventions, rather than technical data.

I. 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 12. Data Rights

A. All data generated in connection with the performance of this Agreement, or that arises out of the use of any materials or enabling technology provided or used by the Awardee in the performance of this Agreement, other Awardee materials or Awardee confidential information, whether conducted by the Government or the Awardee (collectively, the "Study Data"), shall be owned by the Awardee. 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 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 data generated under this agreement.

B. The Awardee agrees to retain and maintain in good condition until seven (7) years after completion or termination of this Agreement, all 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 data, in Awardee's possession and developed under this Agreement, necessary to develop the Prototype within sixty (60) calendar days from the date of the written request.

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

"Use, duplication, or disclosure is subject to the restrictions as stated in Agreement No. [***] between the Government and the Awardee."

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.

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 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.

ARTICLE 13. Regulatory Rights

A. This Agreement includes research with an 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. It is expected this
Agreement will result in the FDA clearance and commercialization of product(s) as set forth in this agreement (the “Technology”). The Awardee will 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.

B. The Senior Director Medical Regulatory (SDMR) is the JPEO-CBRND and DTRA-JSTO representative for all regulatory and quality activities. The Awardee shall coordinate with the SDMR prior to communicating or meeting

with the FDA, or other regulatory authorities, as appropriate. .

C. The Awardee shall invite the SDMR to all FDA meetings and regulatory discussions applicable to this OTA Project.

1. With respect to any products under this Agreement regulated by the FDA for which the Awardee serves as Sponsor, the Awardee agrees to the following:

i. The Awardee 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 Awardee 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 Awardee 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 Awardee shall keep the Government reasonably apprised of planned FDA meetings and post-meeting outcomes relating to activities funded under this Agreement.

ii. Communications. The Awardee 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 Awardee 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 Awardee has 48 hour advance notice of such Sponsor meeting from the FDA prior to the scheduled meeting time.

iii. Non-compliance with section (C)(1)(i) or (C)(1)(ii) may result in termination of the agreement.

2. Product Development Failure. Certain product development failures may trigger certain remedies in Section (3) below for the Government advanced developer funding the development of the work in this Agreement. 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.

3. If any of the product development failures listed in section (b) occur, the Awardee, upon the request of the Government:

i. shall transfer possession, ownership and sponsorship or holdership of any Regulatory Application submitted solely for approval of the Technology (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 provide DoD or its designee with a letter ("Reference Letter") providing permission to reference any Regulatory Application submitted to the FDA for a combination drug-device product that includes the Technology;

iii. shall inform FDA of the transfer of sponsorship or holdership of the Regulatory Application transferred under section (c)(i) above or the Reference Letter issued under section (c)(ii) above; and

iv. 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 Awardee, 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.

D. Awardee shall submit to the Government, within thirty (30) days of contract award, a fully executed sponsor authorization letter enabling FDA to disclose information to the JPEO-CBRND and its government support contractors related to the Technology under Public Law 115-92. A Template of the letter is available upon request. JPEO-CBRND shall submit the executed letter to the FDA only if the Technology becomes a DoD medical product priority under Public Law 115-92.

E. This Article 13 will survive the acquisition or merger of the Awardee by or with a third party. This Article will also be included in any subcontracts/sub agreements relating to the development of the Technology. This Article will survive the expiration of this agreement.

ARTICLE 14. 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 15. Scientific Publications and Press Releases.

A. The Parties shall jointly agree on a publication plan for the Study Data derived from studies executed under this Agreement. 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 Quarterly Program Reviews, 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_cond uct/gui delines-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 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 16. 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 Article 10, 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 OTAO has given prior written approval or (ii) the information is otherwise in the public domain before the date of release. For purposes of this clause, Awardee's Organization includes entities identified as Collaborators in Appendix A Table 1.

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.

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.

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) the Articles of this Agreement, and
the Appendices to the Agreement.