**OTHER TRANSACTION AUTHORITY**
**FOR PROTOTYPE**
**AGREEMENT**

**BETWEEN**

**ICON Government and Public Health Solutions, Inc. (Awardee)**
**1265 Ridge Road**
**Hinckley, OH 44233**
**And**
**NATICK CONTRACTING DIVISION (Government)**
**110 Thomas Johnson Dr.**
**Frederick, MD 21702**

**Effective Date: 27 April 2020**

**Agreement No.: W911QY-20-9-0007**

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

| **Awardee** | **Government** |
|---|---|
| (b) (6) | (b) (6) |
| **Signature** | **Signature** |
| (b) (6) | (b) (4) |
| **Printed Name** | **Printed Name** |
| (b) (6) | **Agreements Officer** |
| **Title** | **Title** |
| April 27, 2020 | 28 April 2020 |
| **Date** | **Date** |

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 ICON Government and Public Health Solutions, Inc, a large 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, attesting to "An entity that is not currently performing and has not performed, for at least the one-year period preceding the solicitation of sources by the Department of Defense for the procurement or transaction, any contract or subcontract for the Department of Defense that is subject to the full coverage under the cost accounting standards prescribed pursuant to Section 1502 of title 41 and the regulations implementing such section.";

WHEREAS, the DoD currently has authority under 10 U.S.C. § 2371b 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 DoD, or to improve platforms, systems, components, or materials in use by the Armed Forces;

WHEREAS, a prototype can generally be described as a physical or virtual model used to evaluate the technical or manufacturing feasibility or military utility of a particular technology or process, concept, end item, or system;

WHEREAS, this Agreement meets the criteria for a prototype project;

NOW THEREFORE, the Parties have agreed as follows:

**ARTICLE 1. Scope.**

A. 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 ultimate purpose of this Agreement is to perform research and development of medical countermeasures (MCMs ) through completion of Phase I, II, and III human clinical trials and surveillance studies that demonstrate the efficacy and safety of products that treat, diagnose and/or protect against SARS-CoV-2/COVID-19, (hereinafter referred to as the "Prototype Project(s)" or "Prototype(s)"). A Prototype may be a clinical trial, a demonstration of efficacy or safety, or other process, or a combination of the foregoing in defense of SARS-CoV-2/COVID-19. Any Prototype may include components such as CDISC compliant locked databases; SDTM/ADaM programming to produce FDA submission compliant TLFs and Final CSRs. The Awardee shall develop the Prototype(s) as described in the Awardee's Statement of Work (SOW), which is incorporated herein and attached hereto as Appendix A. Prototype development may require addendums to the SOW to identify specific activities necessary for the drug, biologic, or device being developed to meet the Government's requirements.

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 not anticipated for this project.

**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 24 months after the Effective Date, 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, or
(v) take any other legally available remedies.

If this Agreement is terminated for Cause, Awardee will grant the Government a non-exclusive, paid up, perpetual license to the Awardee and subawardee patents and documentation necessary for the purpose of developing the Prototype. 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, 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

(b) (6)

Government Project Managers (GPM)

(b) (6)

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 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 (OTAO)
(b) (4)
ACC-APG-Fort Detrick
110 Thomas Johnson Dr.
Frederick, MD 21702
(b) (6)
(b) (4)

Other Transaction Agreement Specialist (OTAS)
(b) (6)
ACC-APG-Fort Detrick
110 Thomas Johnson Dr.
Frederick, MD 21702
(b) (6)
(b) (6)

Agreements Officer's Representative (AOR)
(b) (6)
JPM-CBRND-EB
110 Thomas Johnson Dr.
Frederick, MD 21702
(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 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.

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 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**

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.

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, 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.

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 amount of Government funds obligated by this Agreement and available for

payment is set forth on page 1, Line of Accounting and Appropriation. The Government may incrementally fund this agreement.

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 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.

E. 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.

F. WIDE AREA WORKFLOW PAYMENT INSTRUCTIONS (MAY 2013)

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

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

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

(c) WAWF access. To access WAWF, the 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 Agreement:

(1) Document type. The Awardee shall use the following document type: Voucher

(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

| ***Field Name in WAWF*** | ***Data to be entered in WAWF*** |
|---|---|
| Pay Official DoDAAC | **HQ0490** |
| Issue By DoDAAC | **W911QY** |
| Admin DoDAAC | **W911QY** |
| Inspect By DoDAAC | **W56XNH** |

(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, costs, 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)
OTAS

(b) (6)

(b) (6)

(g) WAWF point of contact.

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

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

(End of Clause)

G. 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**

1. 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 three (3) business days after each formal scheduled meeting/teleconference conducted with JPEO EB.

2. Quarterly Progress Reports

The Awardee shall submit a Quarterly Progress report within twenty (20) calendar days 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 ten (10) calendar days to respond to the report with any comments and the Awardee will have an additional five (5) calendar days to revise the deliverable or respond to those comments.

3. Quarterly Financial Status Report

The Awardee shall submit a Quarterly Financial Status Report no later than twenty (20) calendar days after the end of each quarter of performance. The Government will have

ten (10) calendar days to respond to the report with any comments and the Awardee will have an additional ten (10) calendar days 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.

4. 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 fifteen (15) calendar days 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.

5. 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 forty-fifth (45th) calendar day following the end of the project. The Government shall provide comments to the Awardee by the thirtieth (30th) calendar day following receipt of the Awardee's Draft Final Report. The Awardee shall submit the Final Report on the thirtieth (30th) calendar day after receipt.

6. 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.

7. 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).

8. Regulatory Documentation and Technical Data Packages

The Awardee shall work in consultation with the Government Regulatory and Quality Affairs staff for the development of all regulatory submission packages to the FDA and include Government Regulatory and Quality Affairs staff in all formal discussions with the FDA. The Awardee shall provide the Government copies of all technical data generated by the Awardee prior to and during performance of the project, necessary to pursue FDA approval and notify the Government of FDA decisions as these take place.

If applicable, the Awardee shall prepare an IND/BLA in the Electronic Common Technical Document (eCTD) format for submission to the FDA and the Government. The awardee shall submit all pre-IND, IND, pre-EUA, and/or BLA report submissions to the AOR for review. The Awardee will take into consideration the comments provided by the AOR and provide the final document being sent to FDA to the AOR. The Awardee shall provide all written communications to and/or from the FDA to the Government as it takes place. The Awardee shall courtesy copy the AOR on all email traffic to the FDA and will forward all emails received from the FDA to the AOR. The Awardee will allow a minimum of 2 government representatives to any meeting with the FDA. Meeting minutes will be forwarded to the AOR within seven (7) calendar days of the meeting or teleconference.

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).

9. Miscellaneous Data Submissions

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.

10. 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 thirty (30) calendar days after a Statement of Work modification. Government review/approval is fifteen (15) calendar days after receipt of first submittal. Provide changes to draft within ten (10) calendar days of such request. Provide final document within ten (10) calendar days after approval of changes is received.

11. Integrated Master Schedule

The Awardee shall provide within thirty (30) calendar days 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 thirty (30) calendar days after the end of each month of performance. The Government will have ten (10) calendar days to respond to the report with any comments and the performer will have an additional five (5) calendar days to revise the deliverable or respond to those comments.

12. 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 three (3) business days 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.

**ARTICLE 11. Confidential Information**

A. 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 10. 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.

B. Awardee’s Background IP. Awardee warrants that it has filed patent application(s) or is the assignee of issued patent(s) listed below 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, and the application(s) and any continuing applications (except for continuing applications pursuant to this agreement) are specifically excluded from the definitions of "OTA Invention" contained in this Agreement: None.

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 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 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 11. 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. (b) (4) 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 12. Regulatory Rights**

The Parties will evaluate the regulatory framework for each Prototype Project, including the need for Awardee to secure a Transfer of Regulatory Obligations or other authorization from the regulatory Sponsor of a product regulated by the FDA;

the possibility of Awardee serving as Sponsor of any necessary regulatory filings with the FDA; and the need for one or more of the Parties to enter into other agreements to secure access to intellectual property or regulatory information necessary to perform the research. These terms, along with other material terms of Awardee's engagement, shall be formalized either in the Statement of Work, or under a separate agreement.

Prototype Projects may include research with investigational drugs, biologics or medical devices that are regulated by the U.S. Food and Drug Administration (FDA) and require FDA pre-market approval or clearance before commercial marketing may begin. The Parties anticipate that for most Prototype Projects contemplated under this Agreement, a third party 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 will control research under this agreement. However, in some cases, Awardee or the Government may serve as the regulatory Sponsor for research conducted under this Agreement; and in other cases, the research may not be subject to FDA oversight, and therefore there will be no regulatory SponsorThe Government may serve as the regulatory Sponsor for research conducted under this Agreement; and in other cases, the research may not be subject to FDA oversight, and therefore there will be no regulatory Sponsor.

The Senior Director Medical Regulatory (SDMR) is the JPEO-CBRND 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.

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

Regarding any Technology developed under this agreement for which Awardee serves as regulatory Sponsor, the Awardee agrees to the following:

a. Communications. The Awardee shall provide the Government with all material communications and summaries thereof, both formal and informal, to or from FDA, regarding the Technology within 48 hours, and ensure that the Government representatives are invited to participate in any formal or informal Sponsor meetings with FDA. Awardee shall (1) ensure that the Government representatives are consulted and are invited to participate in any formal or informal Sponsor meetings with FDA related to the Technology; and (2) notify the FDA that the Government has the right to discuss with FDA any development efforts regarding the Technology.

b. Non-compliance with section (a) may result in termination of the Agreement.

c. Product Development Failure. Certain product development failures may trigger certain remedies in Section "d." below for the Government advanced developer funding the development of this Technology. This remedy is not available to the Government for any cause outside of the following:

1. if this agreement is terminated for nonperformance; or

2. the Awardee gives notice, required to be submitted to the Government no later than 30 business days, of any formal management decision to terminate a product development effort, or to file for Federal bankruptcy protection.

d. If any of the product development failures listed in section "c" occur, the Awardee, upon the request of the Government:

1. 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;

2. Shall inform FDA of the transfer of sponsorship or holdership of the Regulatory Application transferred under section (c)(i) above; and

3. Shall negotiate in good faith and upon fair and reasonable terms a non-exclusive license to any patent, copyright, Technical Data or other intellectual property owned or controlled by the Awardee, developed prior to or outside the scope of this Agreement that is necessary for the Government to pursue commercialization of the Technology, with a third party for sale to the Government or otherwise.

e. This clause will survive the acquisition or merger of the Awardee by or with a third party. This clause will also be included in any subcontracts/subawards relating to the development of the Technology. This clause will survive the expiration of this Agreement.

f. In accordance with Public Law 115-92, for any products which Awardee serves as Sponsor, the Government may require Awardee to submit a fully executed sponsor authorization letter enabling FDA to disclose information to JPEO CBRND EB and its government support contractors related to the IND product. JPEO CBRND EB shall submit the executed letter to the FDA only if the IND product becomes a DoD medical product priority under Public Law 115-92, or otherwise mutually agreed upon, and subject to modification of the Agreement.

**ARTICLE 13. Foreign Access to Data.**

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

**ARTICLE 14. 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_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 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 15. Human Subjects.**

(a) Definitions. As used in this clause -

(1) Assurance of compliance means a written assurance that an institution will comply with requirements of 32 CFR Part 219, as well as the terms of the assurance, which the Human Research Protection Official determines to be appropriate for the research supported by the Department of Defense (DoD) component (32 CFR 219.103).

(2) Human Research Protection Official (HRPO) means the individual designated by the head of the applicable DoD component and identified in the component's Human Research Protection Management Plan as the official who is responsible for the oversight and execution of the requirements of this clause, although some DoD components may use a different title for this position.

(3) Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information (32 CFR 219.102(f)). For example, this could include the use of human organs, tissue, and body fluids from individually identifiable living human subjects as well as graphic, written, or recorded information derived from individually identifiable living human subjects.

(4) Institution means any public or private entity or agency (32 CFR 219.102(b)).

(5) Institutional Review Board (IRB) means a board established for the purposes expressed in 32 CFR Part 219 (32 CFR 219.102(g)).

(6) IRB approval means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and Federal requirements (32 CFR 219.102(h)).

(7) Research means a systematic investigation, including research, development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of 32 CFR Part 219, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities (32 CFR 219.102(d)).

(b) The Awardee shall oversee the execution of the research to ensure compliance with this clause. The Awardee shall comply fully with 32 CFR Part 219 and DoD Instruction 3216.02, applicable DoD component policies, 10 U.S.C. 980, and, when applicable, Food and Drug Administration policies and regulations.

(c) The Awardee shall not commence performance of research involving human subjects that is covered under 32 CFR Part 219 or that meets exemption criteria under 32 CFR 219.101(b), or expend funding on such effort, until and unless the conditions of either the following paragraph (c)(1) or (c)(2) have been met:

(1) The Awardee furnishes to the HRPO, with a copy to the Agreements Officer, an assurance of compliance and IRB approval and receives notification from the OTAO that the HRPO has approved the assurance as appropriate for the research under the Statement of Work and also that the HRPO has reviewed the protocol and accepted the IRB approval for compliance with the DoD component policies. The Awardee may

furnish evidence of an existing assurance of compliance for acceptance by the HRPO, if an appropriate assurance has been approved in connection with previous research. The Awardee shall notify the OTAO immediately of any suspensions or terminations of the assurance.

(2) The Awardee furnishes to the HRPO, with a copy to the OTAO, a determination that the human research proposed meets exemption criteria in 32 CFR 219.101(b) and receives written notification from the OTAO that the exemption is determined acceptable. The determination shall include citation of the exemption category under 32 CFR 219.101(b) and a rationale statement. In the event of a disagreement regarding the Awardee's furnished exemption determination, the HRPO retains final judgment on what research activities or classes of research are covered or are exempt under the agreement.

(d) DoD staff, consultants, and advisory groups may independently review and inspect the Awardee's research and research procedures involving human subjects and, based on such findings, DoD may prohibit research that presents unacceptable hazards or otherwise fails to comply with DoD procedures.

(e) Failure of the Awardee to comply with the requirements of this clause will result in the issuance of a stop-work order to immediately suspend, in whole or in part, work and further payment under this Agreement, or will result in other issuance of suspension of work and further payment for as long as determined necessary at the discretion of the OTAO.

(f) The Awardee shall include the substance of this clause, including this paragraph (f), in all subcontracts that may include research involving human subjects in accordance with 32 CFR Part 219, DoD Instruction 3216.02, and 10 U.S.C. 980, including research that meets exemption criteria under 32 CFR 219.101(b). This clause does not apply to subcontracts that involve only the use of cadaver materials.

**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.

G. 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.

H. 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 (ii) the Appendices to the Agreement.

(b) (4)

ICON shall provide full-service capabilities for clinical trial conduct of all studies under this program. The high-level Work Breakdown Structure (WBS) provided in Table 2.1 below provides the primary tasks that will be performed for each study. ICON will develop full, detailed WBSs including tasks/sub-tasks, task/sub-task durations, start and finish dates, predecessors, successors, and resourcing as well as Integrated Master Schedules (IMS)/Gantt Charts for each study prior to initiating the development.

*Table 2.1 High-Level Work Breakdown Structure for JPEO-EBCEO Program Studies*

| Task Name | WBS |
|---|---|
| (b) (4) | |
| (b) (4) | |
| | |
| | |
| | |
| (b) (4) | |
| | |
| | |
| | |
| | |

### 2.4.2 Specific Requirements

The task descriptions provided in Section 2.4.2 below describe ICON's full-service offering, but it should be noted that specific activities will vary depending on the scope of work required in each protocol under the JPEO-EBCEO program of studies. Specific tasks are subject to the requirements and defined in clinical trial plan.

(b) (4)

(b) (4)

(b) (4)

## Appendix B
## Project Schedule/Milestone Payment Schedule

The Government shall pay the Awardee, upon the submission of proper invoices or vouchers, the prices stipulated in this Agreement for supplies delivered and accepted or services rendered and accepted, less any deductions provided in this Agreement. 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 prototype project. The Awardee must maintain a financial system capable of identifying costs applicable to this Agreement, compliant with Cost Principles (48 CFR Part 31) and/or the Cost Accounting Standards (CAS) (48 CFR Part 99). 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 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 OTAO and be in writing, of which email is an acceptable form.

The Parties acknowledge that the nature of this Prototype Project requires flexibility and the ability to react to changing circumstances. Although the Statement of Work sets the scope for activities the Government may require under this Agreement, it is not intended to, and does not, prescribe with specificity each task that ICON will perform. Instead, the Government shall direct ICON to perform specific tasks under the framework established in Articles 3 and 8 of the Agreement, with Government-approved tasks, funding, and deadlines contained in the Integrated Master Schedule. ICON shall not perform any tasks that have not been explicitly authorized by the Government.

ICON will be responsible for submission of SOW's, quotes, and proposals for cost, performance, and schedule for those efforts not already identified, priced or otherwise negotiated. Government approval will be required prior to incurring costs.

## Appendix C
## Key Personnel

**1. Awardee's Organization and Key Personnel.**

a. The Awardee's organization shall be established with authority to effectively accomplish the objectives of the Statement of Work. This organization shall become effective upon award of the Agreement and its integrity shall be maintained for the duration of the effort.

b. The key personnel listed below are considered to be critical to the successful performance of this Agreement. Prior to replacing these key personnel, the Awardee shall obtain the written consent of the OTAO. In order to obtain such consent, the Awardee shall provide advance notice of the proposed changes and shall demonstrate that the qualifications of the proposed substitute personnel are generally equivalent to or better than the qualifications of the personnel being replaced.

c. Prior to permanently removing any of the specified individuals to other contracts, the Awardee shall provide the OTAO not less than thirty (30) calendar days advance notice and shall submit justification (including proposed substitutions) in sufficient detail to permit evaluation of the impact on the program. No reassignment shall be made by the Awardee without written consent of the OTAO. The "Key Personnel" list presented in Table 2 below may be amended from time to time during the course of the Agreement to either add or delete personnel, as appropriate.

**Table 2: Key Personnel**
**Summary**

## Appendix D
## 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 under fixed price terms of this Agreement (FP-GP) if 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 OTAO who will advise the Awardee on a course of action to remedy the problem.

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

| |
|---|
| Reference Government provided spreadsheet maintained by the Awardee and incorporated into the agreement upon approval by the OTAO. |

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 OTAO, 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 OTAO.

Upon conclusion or termination of the Agreement, the Awardee shall submit a request in writing to the OTAO, 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, reasonable 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) OTAO 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 AND SHIPPERS; OR (III) GOVERNMENT PROPERTY IS DISPOSED OF IN ACCORDANCE WITH THE GOVERNMENT'S DIRECTIONS.

# AWARD/CONTRACT

| 1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700) | RATING | PAGE OF PAGES |
|---|---|---|
| | | 1 \| 17 |

| 2. CONTRACT *(Proc. Inst. Ident.)* NO. | 3. EFFECTIVE DATE | 4. REQUISITION/PURCHASE REQUEST/PROJECT NO. |
|---|---|---|
| W911QY2090007P00004 | 27 Apr 2020 | SEE SCHEDULE |

| 5. ISSUED BY | CODE | 6. ADMINISTERED BY *(If other than Item 5)* | CODE |
|---|---|---|---|
| W6QK ACC-APG NATICK<br>CONTRACT NG DIVISION<br>BLDG 1 GENERAL GREENE AVENUE<br>NATICK MA 01760-5011 | W911QY | W6QK ACC-APG NATICK<br>110 THOMAS JOHNSON DR SUITE #240<br>FREDERICK MD 21702 | W911QY |

| 7. NAME AND ADDRESS OF CONTRACTOR *(No., street, city, county, state and zip code)* | 8. DELIVERY | |
|---|---|---|
| ICON GOVERNMENT AND PUBLIC HEALTH SOLUTI<br>1265 R DGE RD STE A<br>H NCKLEY OH 44233-9801 | [ ] FOB ORIGIN [ X ] OTHER *(See below)* | |
| | 9 DISCOUNT FOR PROMPT PAYMENT | |
| | 10 SUBMIT INVOICES *(4 copies unless otherwise specified)* TO THE ADDRESS SHOWN IN: | ITEM |
| CODE 1FBW5 | FACILITY CODE | |

| 11. SHIP TO/MARK FOR | CODE | 12. PAYMENT WILL BE MADE BY | CODE |
|---|---|---|---|
| **See Schedule** | | DEFENSE F NANCE AND ACCOUNT NG SERVICE<br>DFAS-INDY VP GFEBS<br>8899 E 56TH STREET<br>NDIANAPOLIS IN 46249-3800 | HQ0490 |

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

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

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

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| | H | SPECIAL CONTRACT REQUIREMENTS | | | M | EVALUATION FACTORS FOR AWARD | |

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

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

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

| 19A. NAME AND TITLE OF SIGNER *(Type or print)* | 20A. NAME OF CONTRACTING OFFICER |
|---|---|
| | (b) (6) / CONTRACT SPECIALIST<br>TEL: (b) (6) EMAIL: (b) (6) |

| 19B. NAME OF CONTRACTOR | 19C. DATE SIGNED | 20B. UNITED STATES OF AMERICA | 20C. DATE SIGNED |
|---|---|---|---|
| BY _____<br>*(Signature of person authorized to sign)* | | BY (b) (6)<br>*(Signature of Contracting Officer)* | 28-Apr-2020 |

Section SF 30 - BLOCK 14 CONTINUATION PAGE

P00002

A. The purpose of this modification is indicated as below:
1. CLIN 0002 is incrementally funded by (b) (4) .
2. CLIN 0004 is incrementally funded by (b) (4) .
3. CLIN 0005 incrementally funded by (b) (4) .
4. CLIN 0006 incrementally funded by (b) (4) .
5. CLIN 0007 incrementally funded by (b) (4) .
6. CLIN 0008 incrementally funded by (b) (4) .
B. The total funded amount for this document was increased by (b) (4) from (b) (4) to (b) (4)
C. All other terms and conditions remain the same and in full force and effect.

P00003

A. The purpose of this modification is to incorporate additional effort as follows:
1. CLIN 0009 established to incorporate a Phase III Clinical Trial based on the Awardee's proposal dated 18 June 2020.
2. CLIN 000901 is established to incorporate additional funding under ACRN AD.
3. Appendix A of the agreement is hereby revised to incorporate the additional scope
B. The parties hereby agree that changes effected by this modification constitute both the consideration and the equitable adjustment due under any clause of this agreement resulting from the incorporation of the proposal identified in A.3.
C. All other terms and conditions remain the same and in full force and effect.

P00004

A. The puprpose of this modification is as follows:
1. CLIN 0001 is hereby increased by (b) (4) , from (b) (4) , to (b) (4) .
2. Funding under CLIN 000101 is hereby increased by (b) (4) , from (b) (4) , to (b) (4) .
3. CLIN 0004 is hereby decreased by (b) (4) , from (b) (4) to (b) (4) .
4. Funding under CLIN 000401 is hereby decreased by (b) (4) , from (b) (4) to (b) (4)

B. All other terms and conditions remain the same and in full force and effect.

Section B - Supplies or Services and Prices

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|---|---|---|---|---|---|
| 0001 | | | Job | | (b) (4) |
| | Phase I Clinical Trial<br>COST<br>Phase I Clinical Trial in accordance with the Awardee's statement of work, Appendix A of the agreement.<br>FOB: Destination<br>PSC CD: AN12 | | | | |
| | | | | ESTIMATED COST | (b) (4) |

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|---|---|---|---|---|---|
| 000101 | | | | | $0.00 |
| | FUNDING<br>FFP<br>PURCHASE REQUEST NUMBER: (b) (4) | | | | |
| | | | | NET AMT | $0.00 |
| | ACRN AB<br>CIN: (b) (4) | | | | (b) (4) |

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|---|---|---|---|---|---|
| 0002 | | | Job | | (b) (4) |
| | Phase I Clinical Trial<br>COST<br>Phase I Clinical Trial in accordance with the Awardee's statement of work, Appendix A of the agreement.<br>FOB: Destination<br>PSC CD: AN12 | | | | |
| | | | | ESTIMATED COST | (b) (4) |

See Exhibit A

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|---|---|---|---|---|---|
| 000201 | | | | | $0.00 |
| | Funding<br>FFP<br>PURCHASE REQUEST NUMBER: (b) (4) | | | | |
| | | | | NET AMT | $0.00 |
| | ACRN AC<br>CIN: (b) (4) | | | | (b) (4) |

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|---|---|---|---|---|---|
| 0003 | | | Job | | (b) (4) |
| | Phase II Clinical Trial<br>COST<br>Phase II Clinical Trial in accordance with the Awardee's statement of work, Appendix A of the agreement.<br>FOB: Destination<br>PSC CD: AN12 | | | | |
| | | | | ESTIMATED COST | (b) (4) |

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|---|---|---|---|---|---|
| 000301 | | | | | $0.00 |

FUNDING
FFP
PURCHASE REQUEST NUMBER: (b) (4)

NET AMT $0.00

ACRN AB (b) (4)
CIN: (b) (4)

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

Phase II Clinical Trial
COST
Phase II Clinical Trial in accordance with the Awardee's statement of work, Appendix A of the agreement.
FOB: Destination
PSC CD: AN12

ESTIMATED COST (b) (4)

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

FUNDING
FFP
PURCHASE REQUEST NUMBER: (b) (4)

NET AMT $0.00

ACRN AB (b) (4)
CIN: (b) (4)

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|---|---|---|---|---|---|
| 000402 | | | | | $0.00 |

Funding
FFP
PURCHASE REQUEST NUMBER: (b) (4)

NET AMT $0.00

ACRN AC (b) (4)
CIN: (b) (4)

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|---|---|---|---|---|---|
| 0005 | | | Job | | (b) (4) |

Phase II Clinical Trial
COST
Phase II Clinical Trial in accordance with the Awardee's statement of work, Appendix A of the agreement.
FOB: Destination
PSC CD: AN12

ESTIMATED COST (b) (4)

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|---|---|---|---|---|---|
| 000501 | | | | | $0.00 |

Funding
FFP
PURCHASE REQUEST NUMBER: (b) (4)

NET AMT $0.00

ACRN AC (b) (4)
CIN: (b) (4)

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|---|---|---|---|---|---|
| 0006 | | | Job | | (b) (4) |

Phase II Clinical Trial
COST
Phase II Clinical Trial in accordance with the Awardee's statement of work, Appendix A of the agreement.
FOB: Destination
PSC CD: AN12

ESTIMATED COST (b) (4)

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|---|---|---|---|---|---|
| 000601 | | | | | $0.00 |

Funding
FFP
PURCHASE REQUEST NUMBER: (b) (4)

NET AMT $0.00

ACRN AC (b) (4)
CIN: (b) (4)

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|---|---|---|---|---|---|
| 0007 | | | Job | | (b) (4) |

Surveillance Study
COST
Surveillance Study in accordance with the Awardee's statement of work, Appendix A of the agreement.
FOB: Destination
PSC CD: AN12

ESTIMATED COST (b) (4)

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|---|---|---|---|---|---|
| 000701 | | | | | $0.00 |

Funding
FFP
PURCHASE REQUEST NUMBER: (b) (4)

NET AMT $0.00

ACRN AC (b) (4)
CIN: (b) (4)

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|---|---|---|---|---|---|
| 0008 | | | Job | | (b) (4) |

Surveillance Study
COST
Surveillance Study in accordance with the Awardee's statement of work, Appendix A of the agreement.
FOB: Destination
PSC CD: AN12

ESTIMATED COST (b) (4)

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|---|---|---|---|---|---|
| 000801 | | | | | $0.00 |

FY 20 Funding
COST
PURCHASE REQUEST NUMBER: (b) (4)

ESTIMATED COST $0.00

ACRN AA (b) (4)
CIN: (b) (4)

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|---|---|---|---|---|---|
| 000802 | | | | | $0.00 |

Funding
FFP
PURCHASE REQUEST NUMBER: (b) (4)

NET AMT $0.00

ACRN AC (b) (4)
CIN: (b) (4)

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|---|---|---|---|---|---|
| 0009 | | | Job | | (b) (4) |

Phase III Clinical Trial
COST
(b) (4)

FOB: Destination
PSC CD: AN12

ESTIMATED COST (b) (4)

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|---|---|---|---|---|---|
| 000901 | | | | | $0.00 |
| | Funding FY 20<br>COST<br>PURCHASE REQUEST NUMBER: (b) (4) | | | | |
| | | | | ESTIMATED COST | $0.00 |
| | ACRN AD<br>CIN: (b) (4) | | | | (b) (4) |

Section E - Inspection and Acceptance

## INSPECTION AND ACCEPTANCE TERMS

Supplies/services will be inspected/accepted at:

| CLIN | INSPECT AT | INSPECT BY | ACCEPT AT | ACCEPT BY |
|---|---|---|---|---|
| 0001 | Destination | Government | Destination | Government |
| 000101 | N/A | N/A | N/A | N/A |
| 0002 | Destination | Government | Destination | Government |
| 000201 | N/A | N/A | N/A | N/A |
| 0003 | Destination | Government | Destination | Government |
| 000301 | N/A | N/A | N/A | N/A |
| 0004 | Destination | Government | Destination | Government |
| 000401 | N/A | N/A | N/A | N/A |
| 000402 | N/A | N/A | N/A | N/A |
| 0005 | Destination | Government | Destination | Government |
| 000501 | N/A | N/A | N/A | N/A |
| 0006 | Destination | Government | Destination | Government |
| 000601 | N/A | N/A | N/A | N/A |
| 0007 | Destination | Government | Destination | Government |
| 000701 | N/A | N/A | N/A | N/A |
| 0008 | Destination | Government | Destination | Government |
| 000801 | N/A | N/A | N/A | N/A |
| 000802 | N/A | N/A | N/A | N/A |
| 0009 | Destination | Government | Destination | Government |
| 000901 | N/A | N/A | N/A | N/A |

Section F - Deliveries or Performance

## DELIVERY INFORMATION

| CLIN | DELIVERY DATE | QUANTITY | SHIP TO ADDRESS | DODAAC / CAGE |
|---|---|---|---|---|
| 0001 | N/A | N/A | N/A | N/A |
| 000101 | N/A | N/A | N/A | N/A |
| 0002 | N/A | N/A | N/A | N/A |
| 000201 | N/A | N/A | N/A | N/A |
| 0003 | N/A | N/A | N/A | N/A |
| 000301 | N/A | N/A | N/A | N/A |
| 0004 | N/A | N/A | N/A | N/A |
| 000401 | N/A | N/A | N/A | N/A |
| 000402 | N/A | N/A | N/A | N/A |
| 0005 | N/A | N/A | N/A | N/A |
| 000501 | N/A | N/A | N/A | N/A |
| 0006 | N/A | N/A | N/A | N/A |
| 000601 | N/A | N/A | N/A | N/A |
| 0007 | N/A | N/A | N/A | N/A |
| 000701 | N/A | N/A | N/A | N/A |
| 0008 | N/A | N/A | N/A | N/A |
| 000801 | N/A | N/A | N/A | N/A |
| 000802 | N/A | N/A | N/A | N/A |
| 0009 | (b) (4) | | N/A<br>FOB: Destination | |
| 000901 | N/A | N/A | N/A | N/A |

Section G - Contract Administration Data

AGREEMENT ADMINISTRATION
A. In no event shall any understanding of agreement, modification, change order, or other matter in deviation from the terms and conditions of this agreement between the contractor and a person other than the Agreement Officer be effective or binding upon the Government. All such actions must be formalized by a proper agreement document executed by the Agreement Officer.
B. The telephone number and e-mail addresss of the Agreement Officer and Agreement Specialist are:
Agreement Officer: (b) (6)
Telephone (b) (6)
E-mail: (b) (6)
Agreement Specialist: (b) (6)
Telephone: (b) (6)
E-mail: (b) (6)
C. The telephone number and e-mail address of the Government Program Manager is:
Government Program Manager (b) (6)
Telephone (b) (6)
E-mail: (b) (6)

## ACCOUNTING AND APPROPRIATION DATA

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

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

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

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

| ACRN | CLIN/SLIN | CIN | AMOUNT |
|---|---|---|---|
| AA | 000801 | (b) (4) | |
| AB | 000101 | (b) (4) | |
| | 000301 | (b) (4) | |
| | 000401 | (b) (4) | |
| AC | 000201 | (b) (4) | |
| | 000402 | (b) (4) | |
| | 000501 | (b) (4) | |
| | 000601 | (b) (4) | |
| | 000701 | (b) (4) | |
| | 000802 | (b) (4) | |
| AD | 000901 | (b) (4) | |

CLAUSES INCORPORATED BY FULL TEXT

252.232-7006 WIDE AREA WORKFLOW PAYMENT INSTRUCTIONS (DEC 2018)

(a) Definitions. As used in this clause—

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

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

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

"Payment request" and "receiving report" are defined in the clause at 252.232-7003, Electronic Submission of Payment Requests and Receiving Reports.

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

(c) WAWF access. To access WAWF, the Contractor shall—

(1) Have a designated electronic business point of contact in the System for Award Management at https://www.sam.gov; and

(2) Be registered to use WAWF at https://wawf.eb mil/ following the step-by-step procedures for self-registration available at this web site.

(d) WAWF training. The Contractor 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 Contractor shall use the following information when submitting payment requests and receiving reports in WAWF for this contract or task or delivery order:

(1) Document type. The Contractor shall submit payment requests using the following document type(s):

(i) For cost-type line items, including labor-hour or time-and-materials, submit a cost voucher.

(ii) For fixed price line items—

(A) That require shipment of a deliverable, submit the invoice and receiving report specified by the Contracting Officer.

_____

(Contracting Officer: Insert applicable invoice and receiving report document type(s) for fixed price line items that require shipment of a deliverable.)

(B) For services that do not require shipment of a deliverable, submit either the Invoice 2in1, which meets the requirements for the invoice and receiving report, or the applicable invoice and receiving report, as specified by the Contracting Officer.

_____

(Contracting Officer: Insert either "Invoice 2in1" or the applicable invoice and receiving report document type(s) for fixed price line items for services.)

(iii) For customary progress payments based on costs incurred, submit a progress payment request.

(iv) For performance based payments, submit a performance based payment request.

(v) For commercial item financing, submit a commercial item financing request.

(2) Fast Pay requests are only permitted when Federal Acquisition Regulation (FAR) 52.213-1 is included in the contract.

[Note: The Contractor may use a WAWF "combo" document type to create some combinations of invoice and receiving report in one step.]

(3) Document routing. The Contractor 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* |
|---|---|
| Pay Official DoDAAC | HQ0490 |
| Issue By DoDAAC | W911QY |
| Admin DoDAAC** | W911QY |
| Inspect By DoDAAC | W56XNH |

(*Contracting Officer: Insert applicable DoDAAC information. If multiple ship to/acceptance locations apply, insert "See Schedule" or "Not applicable.")

(**Contracting Officer: If the contract provides for progress payments or performance-based payments, insert the DoDAAC for the contract administration office assigned the functions under FAR 42.302(a)(13).)

(4) Payment request. The Contractor shall ensure a payment request includes documentation appropriate to the type of payment request in accordance with the payment clause, contract financing clause, or Federal Acquisition Regulation 52.216-7, Allowable Cost and Payment, as applicable.

(5) Receiving report. The Contractor shall ensure a receiving report meets the requirements of DFARS Appendix F.

(g) WAWF point of contact.

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

(b) (6)

(b) (6)

(2) Contact the WAWF helpdesk at 866-618-5988, if assistance is needed.

(End of clause)

Section I - Contract Clauses

CLAUSES INCORPORATED BY REFERENCE

| | | |
|---|---|---|
| 52.232-22 | Limitation Of Funds | APR 1984 |

# AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

| 1 CONTRACT ID CODE | PAGE OF PAGES |
|---|---|
| | 1 \| 4 |

| 2 AMENDMENT/MODIFICATION NO | 3 EFFECTIVE DATE | 4 REQUISITION/PURCHASE REQ NO | 5 PROJECT NO (If applicable) |
|---|---|---|---|
| P00001 | 06-May-2020 | SEE SCHEDULE | |

| 6 ISSUED BY | CODE | 7 ADMINISTERED BY (If other than item 6) | CODE |
|---|---|---|---|
| W6QK ACC-APG NATICK<br>CONTRACTING DIVISION<br>BLDG 1 GENERAL GREENE AVENUE<br>NATICK MA 01760-5011 | W911QY | W6QK ACC-APG NATICK<br>110 THOMAS JOHNSON DR SUITE #240<br>FREDERICK MD 21702 | W911QY |

| 8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code) | | |
|---|---|---|
| ICON GOVERNMENT AND PUBLIC HEALTH SOLUTI<br>1265 R DGE RD STE A<br>H NCKLEY OH 44233-9801 | | 9A. AMENDMENT OF SOLICITATION NO. |
| | | 9B. DATED (SEE ITEM 11) |
| | X | 10A. MOD. OF CONTRACT/ORDER NO.<br>W911QY2090007 |
| | X | 10B. DATED (SEE ITEM 13)<br>27-Apr-2020 |
| CODE 1FBW5 | FACILITY CODE | |

## 11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer ☐ is extended, ☐ is not extended.

Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)

**See Schedule**

## 13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

☐ A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.

☐ B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).

☐ C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:

X D. OTHER (Specify type of modification and authority)
In accordance with Article 5 of the agreement.

E. IMPORTANT: Contractor ☒ is not, ☐ is required to sign this document and return _____ copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)
Modification Control Number: (b) (6) 201536

A. The purpose of this modification is indicated as below:
1. CLIN 0001 is incrementally funded by (b) (4).
2. CLIN 0003 is incrementally funded by (b) (4).
3. CLIN 0004 incrementally funded by (b) (4).

B. All other terms and conditions remain the same and in full force and effect.

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

| 15A. NAME AND TITLE OF SIGNER (Type or print) | | 16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) | |
|---|---|---|---|
| | | (b) (6)<br>TEL: | |
| 15B. CONTRACTOR/OFFEROR | 15C. DATE SIGNED | 16B. UNITED STATES OF AMERICA | 16C. DATE SIGNED |
| _____<br>(Signature of person authorized to sign) | | BY (b) (6)<br>(Signature of Contracting Officer) | 06-May-2020 |

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

**SUMMARY OF CHANGES**

SECTION B - SUPPLIES OR SERVICES AND PRICES

SUBCLIN 000101 is added as follows:

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|---|---|---|---|---|---|
| 000101 | | | | | $0.00 |
| | FUNDING<br>FFP<br>PURCHASE REQUEST NUMBER: (b) (4) | | | | |
| | | | | NET AMT | $0.00 |
| | ACRN AB<br>CIN: (b) (4) | | | | (b) (4) |

SUBCLIN 000301 is added as follows:

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|---|---|---|---|---|---|
| 000301 | | | | | $0.00 |
| | FUNDING<br>FFP<br>PURCHASE REQUEST NUMBER: (b) (4) | | | | |
| | | | | NET AMT | $0.00 |
| | ACRN AB<br>CIN: (b) (4) | | | | (b) (4) |

SUBCLIN 000401 is added as follows:

| ITEM NO | SUPPLIES/SERVICES | QUANTITY | UNIT | UNIT PRICE | AMOUNT |
|---|---|---|---|---|---|
| 000401 | | | | | $0.00 |
| | FUNDING<br>FFP<br>PURCHASE REQUEST NUMBER: (b) (4) | | | | |
| | | | | NET AMT | $0.00 |
| | ACRN AB<br>CIN: (b) (4) | | | | (b) (4) |

SECTION E - INSPECTION AND ACCEPTANCE

The following Acceptance/Inspection Schedule was added for SUBCLIN 000101:

| INSPECT AT | INSPECT BY | ACCEPT AT | ACCEPT BY |
|---|---|---|---|
| N/A | N/A | N/A | N/A |

The following Acceptance/Inspection Schedule was added for SUBCLIN 000301:

| INSPECT AT | INSPECT BY | ACCEPT AT | ACCEPT BY |
|---|---|---|---|
| N/A | N/A | N/A | N/A |

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

| INSPECT AT | INSPECT BY | ACCEPT AT | ACCEPT BY |
|---|---|---|---|
| N/A | N/A | N/A | N/A |

SECTION G - CONTRACT ADMINISTRATION DATA

Accounting and Appropriation

Summary for the Payment Office

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

SUBCLIN 000101:
Funding on SUBCLIN 000101 is initiated as follows:

ACRN: AB

CIN: (b) (4)

Acctng Data: (b) (4)

Increase: (b) (4)

Total: (b) (4)

Cost Code: (b) (4)

SUBCLIN 000301:
Funding on SUBCLIN 000301 is initiated as follows:

ACRN: AB

CIN: (b) (4)

Acctng Data: (b) (4)

Increase: (b) (4)

Total: (b) (4)

Cost Code: (b) (4)

SUBCLIN 000401:
Funding on SUBCLIN 000401 is initiated as follows:

ACRN: AB

CIN: (b) (4)

Acctng Data: (b) (4)

Increase: (b) (4)

Total: (b) (4)

Cost Code: (b) (4)

(End of Summary of Changes)