EX-10.1 2 exhibit101.htm EX-10.1

EXHIBIT 10.1

Contract No. 75A50120C00034 Development of an mRNA Vaccine for SARS-CoV-2

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

Table of Contents

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PART I – THE SCHEDULE

B. SUPPLIES/SERVICES AND COST/PRICE

B.1 Brief Description of Supplies/Services

The Department of Health and Human Services (HHS), Office of the Assistant Secretary for Preparedness and Response (ASPR), Biomedical Advanced Research and Development Authority (BARDA) requires the contractor(s) to develop a mRNA vaccine to licensure for the prevention of COVID-19. The project will entail pre-clinical and Phase 2 and Phase 3 clinical studies sufficient to demonstrate the safety and efficacy of the proposed vaccine(s); CMC development, scale-up, scale-out and validation of manufacturing capacities, including bulk drug substance and fill and finished drug product, with a capacity of 100 million doses by 2021 and all program management and regulatory activities necessary to achieve FDA licensure of the vaccine. The project shall be accomplished on an accelerated timeline, with parallel activity WBS, aggressive manufacturing scale-up, risk management, and taking advantage of any regulatory flexibilities. Contract terms include a requirement for domestic production of vaccine and assurance of material sourcing for vaccine production during execution of the project.

B.2 Price/Cost

This contract contains the price/cost provisions agreed upon by the Government and the Contractor.

B.2.1 Contract Budget Ceiling

The contract has a cost/price ceiling that the Contractor exceeds at its own risk. The Contractor is responsible for managing its performance in accordance with the final scope of work and costs/prices incorporated into the contract. The Government is not obligated to reimburse the Contractor for costs incurred in excess of costs/prices agreed upon at time of award. The contract ceiling is $483,298,520.00.

B.2.2 Contract Periods

This contract consists of pre-award cost (CLIN 0001), a base period for the Development of mRNA vaccine to BLA (CLIN 0002) and one (1) option period for the Domestic Manufacturing Scale-Out (CLIN 0003).

B.3 Contract Line Item Numbers (CLINs) Schedule

This is a Cost-Plus-Fixed-Fee (CPFF), contract.

B.3.1 Base Period of Performance

The base period of performance (POP) includes pre-award cost (CLIN 0001) and the Development of mRNA vaccine to BLA (CLIN 0002).

a. CLIN 0001 costs shall be pre-award cost incurred by Moderna, with a do not exceed cost of [***].
b. CLIN 0002 costs shall cover the base period statement of work that consists of the development of mRNA vaccine to BLA.
c. These are cost-plus-fixed-fee CLINs with a CPFF structure, [***].
d. Monies shall be provided for the total cost of performance from the Department of Health and Human Services.
e. The Contractor shall maintain records of all contract costs and such records shall be subject to the Audit and Records-Negotiation clause.
f. It is estimated that the amount currently allotted will cover performance of the contract through [***] for the base period.

Pre-Award Period of Performance: [***]
Table 1

CLIN	Estimated Period of Performance	Supplies/Services	Estimated USG Cost	Management Fee (Profit)	Total
0001		Pre-Award Cost	[***]	[***]	[***]

Base Period of Performance: [***]
Table 2

CLIN	Estimated Period of Performance	Supplies/Services	Estimated USG Cost	Management Fee (Profit)	Total
0002		Development of mRNA vaccine to BLA	[***]	[***]	[***]

B.3.2 Option Period 1

This option period includes all Kit Build-Out activities for the facility under CLIN 0003, and may overlap with the base period.

CLIN 0003 is under a CPFF structure, [***]

CLIN	Estimated Period of Performance	Supplies/Services	Estimated USG Cost	Management Fee (Profit)	Total
0003		Domestic Manufacturing Scale-Out	**[***]**	**[***]**	**[***]**

B.3.3 Total Contract Value

The total potential value of this contract, including all CLINs 0001, 0002 and option CLIN 0003is $483,298,520.00.

B.4 Advanced Understandings

This contract contains advanced understandings between the Government and the Contractor. Specific elements of cost, which normally require prior written approval of the Contracting Officer before incurrence of the cost, will be included in this Section if the Contracting Officer has granted approval prior to contract award.

B.4.1 Rights of first refusal – mRNA Vaccines

[***]

B.4.2 HHS reserves the right to exercise priorities and allocations authority with respect to this contract, to include rating this order in accordance with 45 CFR Part 101, Subpart A—Health Resources Priorities and Allocations System

B.4.3 Earned Value Management (EVM) Lite Requirements

The Contractor shall use an Earned Value Management (EVM) System for all retrofit and development activities of the anticipated requirement, that is consistent with the "7 Principles of Earned Value Management Tier 2 System Implantation Intent Guide" attached to this contract. Alternative systems may be submitted to the Contracting Officer for consideration and approval.

B.4.4 Public Readiness and Emergency Preparedness Act ("PREP ACT") Coverage

The Federal Government may not use, or authorize the use of, any products or materials provided under either this agreement or any future purchase from Recipient's domestic manufacturing capacity unless such use occurs in the United States and is protected from liability under a declaration issued under the Public Readiness and Emergency Preparedness Act, 42 U.S.C. § 247d-6d.

B.4.5 Provisions to Applicable Costs

This section prohibits or restricts the use of contract funds which includes the following items (costs unallowable unless otherwise approved by the Contracting Officer):

a. Acquisition, by purchase or lease, of any interest in real property;
b. Purchase of lease of any item of general purpose office furniture or office equipment regardless of dollar value;
c. Accountable Government Property (as defined by HHS Government property policies
d. Overtime;
e. General scientific meetings/conferences;
f. Travel costs including foreign travel;
g. Costs incurred in the performance of any cost-reimbursement type subcontract (including consulting agreements);
h. Costs to be paid for the performance of a fixed-price subcontract that exceeds $250,000.00 (for equipment purchases, $25,000.00 per unit);
i. Refreshments and Meal Expenditures;
j. Promotional Items Printing;
k. Payment of regulatory submission fees to the FDA or other U.S. regulatory agency;
l. BLA licensing or renewal fees;
m. Pre-contract costs (other than those expressly set forth herein).

B.4.6 Facility, Equipment and Product Ownership

In the event the USG terminates this contract for other than default, all Contractor-acquired Government Furnished Property (GFP) [as defined by 52.245-1], to include process equipment, is to be assessed by a reputable third party firm that specializes in assigning fair market value of biopharmaceutical materials, supplies and equipment for the resale market. The USG will use this fair market value assessment in settlement, around the disposition of the GFP.

Ownership and applicable usage rights of all materials/product (e.g. vaccines, validated lots) manufactured and/or acquired with Government funds, throughout the Contract's entire period of performance, shall be retained by the USG. The Contracting Officer will direct the Contractor on the disposition (i.e. storage, transfer, disposal, etc.) of all Contractor-acquired/manufactured USG materials/product.

B.4.7 [reserved] .

B.4.8 Advanced Understanding: Milestone Review: the development of a COVID-19 vaccine is an accelerated program. Progress for vaccine development will be continually assessed for go/no go decisions so that funding is properly allocated across the MCM development effort to those candidates most likely to be available in time to impact the COVID-19 public health emergency. Formal 'go/no go' assessments will be made at multiple points, including:
[***]

B.4.9 Contractor Responsibility for Major Site Service & Utility System

BARDA acknowledges that Moderna is offering to undergo potential upgrades to its manufacturing processes as outlined in the Technical Proposal. A preliminary assessment of major site service and utility systems of Contractor's existing facility has deemed them adequate in supply and fitness to meet stated scope. However, if, during the course of executing this contract, Moderna discovers that major site service or utility replacement/upgrades at such facility are required to accomplish the scope of work, then the costs for said replacement/upgrades shall be covered by Moderna. As with any significant renovation Moderna has implied duty to disclose superior knowledge of site conditions. As contract work is performed, Moderna will ensure that the BARDA Contracting Officer's Representative (COR) is fully informed of all issues that could affect cost or schedule. BARDA commits to work with Moderna to assess specific complex situations.

Examples of major site-wide service/utility systems outside the envelope of Buildings to be warranted by Moderna:

- Plant steam supply;
- Potable water/ Non-potable water supply (depending on the site, non-potable water could be fire hydrants);
- Sewer line\Sanitation line (post inactivation/ treatment) ;
- Site chiller/ chilled water supply;
- High and Low voltage Electrical feed(s) ;
- Network Infrastructure;
- Site-wide automation capacity;
- Perimeter fencing/ site security;
- Storm water;
- Gas (natural gas, site gas feeds);
- Fuel (generator fuel piping, this may be out of scope);
- Earthwork required to relocate, improve, or maintain site infrastructure such as manholes, duct banks, etc.

All NEPA, state and local government environmental requirements are met for this project; any concerning issues have been disclosed to the USG before award.

B.4.10 Evaluating the Expansion of Surge Vaccine Manufacturing Capacity

The parties agree to develop and evaluate plans to further expand and diversify US-based domestic vaccine manufacturing capacity to respond to the pandemic. A draft framework will be completed within 60 days. This CMC domestic build-out/scale-out will further ensure that the United States has sufficient manufacturing capacity in response to the pandemic.

B.4.11 Subcontracts

Prior written consent from the Contracting Officer in the form of Contracting Officer Authorization (COA) is required for any subcontract that:

•Is of the cost-reimbursement type; or
•Is Fixed-Price and exceeds $250,000 or 5% of the total estimated cost of the Contract, whichever value is greater.

The Contracting Officer shall request appropriate supporting documentation in order to review and determine authorization, pursuant with FAR Clause 52.244-2, Subcontracts. After receiving written consent of the subcontract by the Contracting Officer, the Contractor shall provide a copy of the signed, executed subcontract and consulting agreement to the Contracting Officer.

On March 13, 2020, the U.S. President declared a national emergency due to the outbreak of the coronavirus. The subcontractors and consultants listed below are currently engaged in the mRNA-1273 development program and are tentatively approved to continue work. These subcontractors must complete the COA process per FAR Clause 52.244-2 within 90 days. New vendors initiating work within the first 60 days of the contract will be allowed to start, and COA requests will be submitted within 90 days.

Note: Consulting services are treated as subcontracts and subject to the 'consent to subcontract' provisions set forth in this Article.

[***]

[***]

B.4.12 Performance Standard

The contractor will not be in default under this agreement to the extent that it makes reasonable efforts to perform the services and produce and provide the items described in this contract.

B.4.13 Limited Rights Data

Notwithstanding any contrary representation by the Contractor on the System for Award Management or any contrary provision in this contract, the following categories of information developed at private expense will, if provided to the Government, be considered limited rights data subject to the restrictions specified in FAR 52.227-14, Alternate II. These restrictions apply to any component of information covered by this provision, regardless of whether a component is included in a contract deliverable. The Government will not reverse engineer or otherwise evaluate materials provided under this Contract to reproduce the type of information described below without Moderna's prior written consent.

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

C. DESCRIPTION / SPECIFICATIONS / WORK STATEMENT

C.1 Background

Coronaviruses are potential epidemic threats and have been recognized on the World Health Organization's list of top emerging diseases likely to cause major epidemics and Coalition for Epidemic Preparedness Innovations priority pathogens list. No vaccines to prevent Coronavirus infection are currently available. The emergence of the SARS-CoV-2 virus creates an urgent need to rapidly develop vaccines to prevent COVID-19 disease. Developing and delivering a vaccine for highly transmissible, emerging diseases such as the SAR-CoV-2 virus requires breaking from traditional approaches. It requires parallel development activities, aggressive manufacturing scale-up, risk management and implementation of regulatory flexibilities. Many of these requirements are met by manufacturing 'platforms' that are capable of producing vaccines against different agents using essentially the same manufacturing systems. Suitable platforms are constituted by defined product production processes that allow significant planning for manufacturing scale and time to vaccine availability and will be supported by human safety and immunogenicity data targeting an one or more infectious agents. To meet the purposes of this contract, it is critical that the vaccine be produced in the United States. Domestic production of the vaccine is the only assurance that Americans will have access to the finished product.

Moderna's mRNA-based vaccine platform has been used to rapidly prepare vaccine candidates against Cytomegalovirus, Zika, Respiratory Syncytial Virus, Influenza, Human Metapneumovirus and Parainfluenza virus. Four of these candidates have been evaluated in Phase 1 clinical studies and shown to be safe and immunogenic. Moderna collaborated with the Vaccine Research Center, NIAID ("VRC/NIAID") to design a lead SARS-CoV-2 vaccine candidate encoding a stabilized pre-fusion, SARS-CoV-2 Spike protein, which is more immunogenic than wild-type or subunit proteins. Moderna's mRNA vaccine is currently being evaluated in pre-clinical studies and Phase 1 trials sponsored by the NIAID. For the purposes of this contract, Moderna will perform all work required to support the advanced development, scale-up manufacturing and FDA licensure of their lead SARS-CoV-2 vaccine candidate(s). This work includes preclinical development of mRNA vaccines to demonstrate safety and efficacy against COVID-19, mRNA vaccine process and manufacturing scale-up development, product lot release assay development and process validation, production of clinical material and consistency lots clinical evaluation studies for safety, immunogenicity and efficacy; and fill/finish capacity evaluation, expansion, and validation.

The Governments has determined a bona fide need for each non-severable discrete work segment which will conclude upon the completion of a defined task(s) that provides independent merit and value to the Government. The Contractor must achieve a defined end-point required in each discrete work segment, as outlined in Section F of this contract, before the Government will consider exercising any of the follow-on option segment(s). The Contractor's success in completing the required tasks under each work segment must be demonstrated through the Deliverables and Milestones specified under Section B and F of this contract. Those deliverables will support the GO/NO GO Contract Milestones and Decision Gates specified therein. The GO/NO GO Contract Milestones and Decision Gates will constitute the basis for the Government's decision, at its sole discretion, to exercise any follow-on option segment(s).

The base and option segments under Contract Line Items (CLINs) 0001 through 0003 are event driven work segments rather than time driven CLINs. The funds for each independent, non-severable discrete work segment (requirement), regardless of duration, are separated by CLIN, and shall only be used for the scope of work covered in each discrete work segment. The periods of performance listed under each of the CLINs under Article B.2 and Article B.3 are estimated time periods. Those individual time periods may be extended by mutual agreement of the parties to complete the tasks required under each work segment. It is possible that more than one independent, non-severable discrete work segment (requirement), may be awarded at one time and that individual CLINs may overlap and/or proceed concurrently

C.2 Statement of Work

Independently, and not as an agent of the United States Government, the contractor shall furnish all necessary services, qualified professional, technical, and administrative personnel, material, equipment and facilities, not otherwise provided by the Government under the terms of this contract, as needed to perform the tasks set forth below.

mRNA Vaccine Development (WBS 1.0)
The Contractor, Moderna, Inc. ("Moderna") shall execute the preclinical, clinical, and chemistry, manufacturing and controls (CMC) activities required to license a vaccine against the SARS-CoV-2 virus (herein referred to as "mRNA vaccine"). Building upon early clinical development already underway, this proposal will support the late stage development, including the demonstration of clinical efficacy and generation of a dataset supportive of licensure. Moderna will additionally evaluate the platform manufacturing capabilities relative to the needs for supply in response to a pandemic.

Program Management (WBS 1.1)

mRNA Program Management (WBS 1.1.1)

Moderna's mRNA program team is composed of a multidisciplinary, highly matrixed, group of functional leads with experience in, and responsibility for, integrating plans and operationalizing strategies across Research, Toxicology, CMC, Regulatory Affairs,

Clinical Development and Quality. Collectively, the team has advanced ten programs to first-in-human studies within five years. The group will be led by a program lead (PL) who will oversee and coordinate the activities necessary to meet program objectives. The PL will be the point of accountability for the development of mRNA vaccine. [***] . A program management office (PMO) will be responsible for managing the cost and schedule constraints of the contract via an integrated master schedule and corresponding budget, identifying and managing program risk, and ensuring contract compliance. With the input from the mRNA project team, the PMO will be responsible for coordinating the drafting of and management to an integrated development plan. Upon execution of the contract, weekly meetings with BARDA will be held to monitor program performance and monthly and annual reports will be will delivered to BARDA for the record.

Nonclinical Toxicology (WBS 1.2)
Development and Reproductive Toxicology of mRNA (WBS 1.2.2.1)
To assess the risk of administering the vaccine to pregnant women, a complete GLP rat developmental and reproductive toxicology (DART) study is planned. Female Sprague Dawley rats will be dosed at the highest anticipated clinical dose level and include a control arm of phosphate-buffered saline (PBS). As is typical for DART evaluations for vaccines, the animals will be immunized three times prior to mating and two times during gestation. Each group will have two cohorts (one group will undergo Cesarean section with examination of the uteri and embryos; the other group will have natural delivery and will be terminated at weaning).

Nonclinical (WBS 1.3)
For the purposes of this proposal it is assumed that the VRC continues to support nonclinical activities to develop murine and non-human primate efficacy studies, and animal models to assess the potential of vaccine-enhanced disease. The scope of work below will execute additional robustness experiments in these developed models.

Assess Disease Enhancement (WBS 1.3.3.1)
[***]

We plan to perform studies in mouse and NHPs to assess the theoretical risk of vaccine induced disease enhancement triggered by CoV infection following vaccination with imRNA vaccine. [***]

[***]

[***]

Establish a Surrogate of Protection (WBS 1.3.3.2)
The primary endpoint for accelerated approval of a SARS-CoV-2 vaccine would be a neutralization assay. This endpoint must be supported with a body of pre-clinical work that demonstrates a correlation between neutralizing titers and efficacy and that quantifies a protective serologic threshold titer using the same neutralization assay. Murine and NHP efficacy models are being developed in parallel to the Phase 1 clinical study. Building on data from these preliminary models and studies, Moderna will conduct NHP efficacy and murine passive transfer studies to confirm and refine the surrogate of protection.

Clinical (WBS 1.4)

[***]

Phase 2 Safety and Immunogenicity Study (WBS 1.4.2.1)

[***]

Phase 3 Pivotal Study:(WBS 1.4.3.1)

I. Scenario in which SARS-CoV-2 virus is circulating: In this scenario a randomized controlled trial with prevention of disease endpoint would serve to demonstrate effectiveness of the vaccine.

[***]

II. Scenario in the absence of SARS-CoV-2 virus: In this scenario an efficacy study becomes infeasible.

[***]

Lot to Lot Consistency (WBS 1.4.3.2)

[***]

Pediatrics (WBS 1.4.3.3)
[***]

Regulatory (WBS 1.5)

IND Preparation and Filing (WBS 1.5.1.1)

Moderna's Regulatory Affairs group, in close collaboration with BARDA, will work to draft a comprehensive regulatory master plan to guide the preclinical, CMC and clinical development of mRNA within the first 90 days of the contract. An original investigational new drug application (IND) will be filed with the United States Food and Drug Administration (FDA) to support the clinical development of the Moderna product from Phase 2 onwards.

IND Maintenance (WBS 1.5.1.2)

The Moderna-owned IND will be maintained to support the desired clinical development plan. As needed, meetings will be conducted to receive feedback and gain concurrence on the specifics of the development activities with the FDA.

BLA Submission (WBS 1.5.2.1)

Moderna will submit a Biologics License Application (BLA) and seek approval for the mRNA vaccine.

CMC (WBS 1.6)

CTM Manufacture for Phase 2 (WBS 1.6.3.2)

[***]

Process Development for Late Stage Clinical Supply (WBS 1.6.3.3)

mRNA Process Development

Technical Development will confirm and optimize the process parameters for mRNA manufacture. [***]
[***]

BLA Readiness (WBS 1.6.3.8)
In support of the Biologics License Application (BLA) due to the nature of the proposed timeline, it is likely that Moderna will need to complete some of process validation activities, primarily process characterization, after the completion of process performance qualification and before BLA filing. Moderna intends to rapidly develop a robust process for clinical manufacturing and PPQ, and then fully describe the acceptable design space for the process prior to BLA filing. Other activities to support this BLA filing, such as completing raw material qualification activities; if not included in the BLA submission, will require a supplement to the initial BLA. In the initial BLA filing Moderna will describe its control strategy to cover the gap between initial BLA filing and the BLA supplement.

Process Development for Full Commercial Scale (WBS 1.6.4.1)
The following section outlines the process development activities [***]. The goal of this work is to demonstrate the capability to produce mRNA at a scale that can support clinical demand.
[***]

[***]

Analytical Method Development and Validation (WBS 1.6.5.2)

[***]

Characterization Assay Development and Implementation (WBS 1.6.5.3)
[***]

Stability Studies (WBS 1.6.5.4)
Throughout the program, many studies will be undertaken [***] This includes studies using development bench scale material, engineering lot material, and GMP material. This body of data will be used to apply interim and long-term shelf life to the drug product and process intermediates.

1. Intellectual Property

The parties agree that that data generated prior to entering into or outside the scope of the agreement will, when delivered to the USG, be considered to be limited rights data subject to the restrictions covered under FAR Clause 52.227-14 Alt II paragraph (g)(3). The government will obtain unlimited rights to data funded under this contract pursuant to FAR Clause 52.227-14. The parties rights to subject inventions developed during performance of this contract will be governed by the terms of FAR Clause 52.227-11

2. Use of Select Agents

As Moderna selects programs for demonstration of the platform, Moderna will defer to an HHS chaired committee of contracting, security, safety and scientific program management to assess the applicability of the facilities, regulations, policies, and procedures for meeting the U.S. requirements described in 42 CFR part 73, 7 CFR part 331, and/or 9 CFR part 121.

3. Laboratory Licenses Requirements

Moderna will comply with all applicable requirements of Section 353 of the Public Health Service Act (CLIA, as amended). This requirement shall also be included in any relevant subcontract for services under the contract.

4. Target Product Profile

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

CONTRA-INDICATION	None

D. PACKAGING AND MARKING (if applicable)

Unless otherwise specified by the Contracting Officer, all deliverable items to be furnished to the Government under this contract (including invoices) shall be made by first class mail, overnight carrier, or email, as described in Section F.

All physical deliverables shall be preserved, packaged, and marked in accordance with normal commercial practices to meet the packaging requirements of the carrier, including that which is necessary to prevent deterioration and damages due to the hazard of shipping, handling, and storing. The Contractor shall guarantee that all required materials shall be delivered in immediate usable and acceptable condition.

E. INSPECTION AND ACCEPTANCE

E.1 Federal Acquisition Regulation Clauses Incorporated by Reference

This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this address: http://acquisition.gov/far/

The following FAR clauses, pertinent to Section E, are hereby incorporated by reference:

FAR Clause	Title	Date
52.246-2	Inspection of Supplies – Fixed Price	Aug 1996
52.246-5	Inspection of Services – Cost Reimbursement	Apr 1984
52.246-9	Inspection of Research and Development	May 2001

All work under this contract may be subject to inspection and final acceptance by the Contracting Officer or the duly authorized representative of the Government. The Contracting Officer's Representative (COR) is a duly authorized representative of the Government and is responsible for the inspection and acceptance of all items/activities to be delivered and or completed under this contract.

F. DELIVERABLES / PERFORMANCE

F.1 Federal Acquisition Regulation Clauses Incorporated by Reference

This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this address: http://acquisition.gov/far/

The following FAR clause, pertinent to Section F, is hereby incorporated by reference:

FAR Clause	Title	Date
52.242-15	Stop-Work Order, Alternate I (Apr 1984)	Aug 1989

F.1.1 A pandemic facility and/or operational management plan including change procedures from normal to pandemic operations. Prepare an operational plan to continue operations in the event of a declared pandemic emergency (Draft within 15 days of award, Final within 30 days of award).

F.1.2 Data Management Plan

The Contractor shall develop and implement data management and quality control systems/procedures, including transmission, storage, confidentiality, and retrieval of all contract data; provide for the statistical design and analysis of data resulting from the research; provide raw data or specific analyses of data generated with contract funding to the Project Officer, upon request.

F.1.3 Standard Operating Procedures

The Contractor shall make internal and, to the extent possible, Subcontractor Standard Operating Procedures (SOPs) available for review by the Government on-site at Contractor's facility, upon request from the COR or CO. At Contractor's election, SOPs may be provided electronically.

F.1.4 Evaluation of Fill Finish Alternatives

The Contractor shall submit a Draft Final and Final Report describing the fill finish alternatives evaluated, the evaluation method and criteria used, cost comparison, and recommendation for which fill finish alternative to move forward. The draft report shall be due within thirty (30) days after completion of analysis. Subcontractor-prepared reports, on behalf of the Contractor, shall be submitted to the COR and CO for review and comment, no later than five (5) business days after receipt by the Contractor. BARDA shall provide written comments to the Draft Final Report within fifteen (15) days after the submission. The Final Report shall be due thirty (30) days after receiving comments on the Draft Final Report from BARDA. If corrective action is recommended, the Contractor must address, in written, all concerns raised by the Government.

F.1.5 Supply Chain Resiliency Plan

The partner contractor shall have a comprehensive Supply Chain Resiliency Program that provides for identification and reporting of critical components associated with the secure supply of drug substance, drug product, and work-in-process through to finished goods. A critical component is any material that is essential to the product or the manufacturing process associated with that product. Included in the definition are consumables and disposables associated with manufacturing. NOT included in the definition are facility and capital equipment.

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

Identification of key equipment suppliers and their locations, local resources and the associated planning and control processes at the time of award is important to the security of the medical countermeasure supply chain. These processes shall address planning and scheduling for active pharmaceutical ingredients, upstream, downstream, component assembly, finished drug product and delivery events as necessary for the delivery of product. Where multi-site manufacturing is integral to the delivery of contractual materials, it should be included as part of the planning and scheduling process. Communication for these requirements shall be updated as part of an annual review, or as necessary, as part of regular contractual communications.

The focus on the aspects of resiliency shall be on critical components and aspects of complying with the contractual delivery schedule. Delivery methods shall be addressed, inclusive of items that are foreign-sourced, both high and low volume, which would significantly affect throughput and adherence to the contractually agreed deliveries.

For upstream and downstream processing, both single-use and re-usable in-place processing equipment, and manufacturing disposables also shall be addressed. For finished goods, the inspection, labeling, packaging, and associated machinery shall be addressed taking into account capacity capabilities.

The partner contractor shall communicate the methodology for inventory control, production planning, scheduling processes and ordering mechanisms, as part of those agreed deliveries. For critical items these processes should provide visibility for key items over an adequate planning horizon that ensures effective control of the established supply chain for contractual deliveries. Production rates and lead times shall be understood and communicated to the HHS/ASPR/BARDA Contracting Officer or the Contracting Officer's Representative as necessary.

Production throughput critical constraints should be well understood by activity and by design, and communicated to contractual personnel. As necessary, communication should focus on identification, exploitation, elevation, and secondary constraints of throughput, as appropriate.

Reports for critical items may be summarized with the following template:

Critical Material Name	Vendor	Supplier, Manufacturing / Distribution Location	Supplier Lead Time	Shelf Life	Transportation / Shipping restrictions

The CO and COR reserve the right to request unredacted copies of technical documents, during the period of performance, for distribution within the Government, and Contractor will reasonably consider any such requests. Documents shall be provided within ten (10) days after CO issues the request. The Contractor may arrange for additional time if deemed necessary, and agreed to by the CO.

F,2 Deliverables Schedule

Successful performance of the final contract shall be deemed to occur upon performance of the work set forth in the Statement of Work attached to this contract as Attachment 1 (SECTION J-List of Attachments), and upon delivery and acceptance, as required by the Statement of Work, by the Contracting Officer, or the duly authorized representative pursuant to SECTION E-Inspection and Acceptance, of the following items listed below under heading 1 "Summary of Contract Deliverables" in accordance with the stated delivery schedule.

The items specified below under heading 1 "Summary of Contract Deliverables", as described in the Statement of Work which is Attachment 1 to this contract will be required to be delivered by the date(s) specified below and in accordance with any specifications stated in SECTION D- PACKAGING, MARKING AND SHIPPING, of this contract. All reports identified below relate solely to the development activity funded under this contract:

1. Summary of Contract Deliverables

Unless otherwise stated, each deliverable in the table below shall be provided as one (1) electronic copy to the COR, CS, and CO as set forth in SECTION D.

In addition to or in replacement of electronic copies, the CO may direct the Contractor to submit the below deliverables via BARDA Digital Resources Portal in machine readable format.

Table 5

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
01	**Meetings**		
01.1	Post Award Teleconference	The contractor shall complete an initial teleconference after contract award 1. Outline activities for the next 30 days 2. Discuss agenda items for the post-award Kickoff Meeting (01.2)	• Within one week of contract award • Contractor shall provide agenda and establish a teleconference number at least 3 business days in advance of the teleconference unless notified that BARDA will supply one • COR edits/approves and instructs contractor to distribute agenda prior to meeting by at least 2 business days • Contractor provides meeting minutes to COR within 3 business days after the meeting • COR reviews, comments and approves minutes within 10 business days
01.2	Kickoff Meeting	The Contractor shall complete a Kickoff meeting after contract award	• Within a month of contract award, pending concurrence by the contracting officer • Contractor shall provide itinerary and agenda at least 5 business days in advance of site visit or virtual meeting • COR edits/approves and instructs contractor to distribute agenda prior to meeting by at least 3 business days • Contractor provides meeting minutes to COR within 3 business days after the meeting • COR reviews, comments, and approves minutes within 10 business days
01.3	Every 2 weeks Teleconference	The Contractor shall participate in teleconferences every 2 weeks, with BARDA to discuss the performance on the contract. Meeting frequency can be increased as needed during the course of the project	• Contractor provides agenda to COR no later than 2 business days in advance of meeting • COR edits/approves and instructs contractor to distribute agenda prior to meeting • Contractor distributes agenda and presentation materials at least 24 hours in advance • Contractor provides meeting minutes to COR within 3 business days of the meeting • COR reviews, comments, and approves minutes within 6 business days
01.4	Quarterly Meetings	At the discretion of the government the Contractor shall hold recurring teleconference or face-to-face Project Review Meetings up to four per year either in Washington D.C or at work sites of the Contractor or sub-contractors. Face-to-face meetings shall alternate between Washington DC and Contractor, sub-contractor sites. The meetings will be used to discuss contract progress in relation to the Program Management deliverables described below as well as study designs, technical, regulatory, and ethical aspects of the program.	• Contractor shall provide itinerary and agenda at least 5 business days, and presentation materials at least 3 business days in advance of site visit • COR edits/approves and instructs contractor to distribute agenda prior to meeting by at least 3 business days • Contractor provides meeting minutes to COR within 3 business days after the meeting • COR reviews, comments, and approves minutes within 10 business days
01.5	FDA Meetings	The Contractor shall forward the dates and times of any meeting with the	• Contractor shall notify BARDA of upcoming FDA meeting within 24 hours of scheduling

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		FDA to BARDA and make arrangements for appropriate BARDA staff to attend the FDA meetings. BARDA staff shall include up to a maximum of four people (typically COR and up to 3 subject matter experts)	Type A, B or C meetings OR within 24 hours of meeting occurrence for ad hoc meetings • The Contractor shall forward initial Contractor and FDA-issued draft minutes and final minutes of any meeting with the FDA to BARDA within 2 business days of receipt
01.6	Daily check in with project staff for COVID-19 Contract	Upon request of the Government, the Contractor shall participate in a daily check-in update with the project staff (via teleconference or email). The updates will address key cost, schedule and technical updates. Daily updates may be shared with senior Government leaders during the COVID- 19 response and should be provided on a non-confidential basis, unless the update includes confidential information in which case Contractor shall provide the update in both confidential and non-confidential formats. Daily check-ins may occur on weekdays, excluding federal holidays. Upon request of the Government, check-ins may also occur on weekends and on federal holidays, provided at least 24 hours' notice.	• No agenda will be required for the meeting • No meeting minutes are required • Contractor will provide bulleted email updates following any call or in lieu of a call by 2PM for that day

02	Technical Reporting		
02.1 (Monthly) 02.2 (Annual)	Monthly & Annual Technical Progress Reports/Annual Meeting	1. The Integrated Program Management Report (IPMR) is a contractually required report prepared by the contractor. IPMR Formats 1, 3, 5, and 6 are required. These formats will contain performance data and information derived from the contractor's internal Earned Value Management System (EVMS) and Integrated Master Schedule (IMS). The Contractor's EVMS shall comply with Earned Value Management's Seven (7) Principles. 2. An Executive Summary highlighting the progress, issues and relevant manufacturing, non-clinical, clinical and regulatory activities. The Executive Summary should highlight only critical issues for that reporting period and resolution approach; limited to 2 pages 3. BARDA Contractor Clinical Trials Information Sheet – covering ongoing BARDA-sponsored clinical studies. This form shall provide data on relevant activities during the period covered, by study site, including: cumulative enrollment; new enrollments; screen failures; patients dropped from study; AE and SAEs; activation or inactivation of study sites; investigator appointments or changes; and status of IRB/IEC review/approval/renewal 4. Progress in meeting contract milestones organized by WBS, overall project assessment, problems encountered and recommended solutions. The reports shall detail the planned and actual progress during the period covered, explaining any differences between the two and the corrective steps 5. A three-month rolling forecast of the key planned activities, referencing the WBS/IMS 6. A tracking log of progress on regulatory submissions with the FDA number, description of submission, date of submission, status of submission and next steps 7. Estimated and Actual Expenses a. This report shall also contain a narrative or table detailing whether there is a significant discrepancy (>10%) at this time between the %	• Monthly Reports shall be submitted on the 20th day of the month covering the preceding month; Annual Reports submitted on the 30th calendar day of the month after each contract anniversary. Monthly progress reports are not required for the months when the Annual Report(s) are due, and Monthly/Annual Report(s) are not due during a month when the Final Report (final version, not draft) is due (see deliverable 02.4). The COR and CO will review the monthly reports with the Contractor and provide feedback • Contractor shall provide FINAL versions of reports within 10 business days after receiving BARDA comments/edits • Integrated Performance Management Report (IPMR) shall be developed according to the instructions of Data Item Description (DiD) #81861A • The CPR shall be provided on the 20th day of the month covering the preceding month, including the same month as the Annual Report(s) is due • The IPMR required formats for this Contract shall be Formats 1 (WBS), 3 (Performance Measurement Baseline Changes and Reconciliation), 5 (Variance Analysis Report – Narrative Form), and 6 (Integrated Master Schedule)

		of work completed and the cumulative costs incurred to date. Monthly and actual expenses should be broken down to the appropriate WBS level. This section of the report should also contain estimates for the Subcontractors' expenses from the previous month if the Subcontractor did not submit a bill in the previous month. If the subcontractor(s) was not working or did not incur any costs in the previous month, then a statement to this effect should be included in this report for those respective subcontractors If the COR and CO are satisfied that the contractor's reporting is sufficient to convey this information, this section may be waived.	
02.3 (Draft) 02.4 (Final)	Draft and Final Technical Progress Report	A draft Final Technical Progress Report containing a summation of the work performed and the results obtained over the entire contract. This report shall be in sufficient detail to fully describe the progress achieved under all milestones. Report should contain a timeline of originally planned and baselined activities and milestones overlaid with actual progress attained during the contract. Descriptions and rationale for activities and milestones that were not completed as planned should be provided. The draft report shall be duly marked as 'Draft' The Final Technical Progress Report incorporating feedback received from BARDA and containing a summation of the work performed and the results obtained for the entire contract PoP. The final report shall document the results of the entire contract. The final report shall be duly marked as 'Final'. A cover letter with the report will contain a summary (not to exceed 200 words) of salient results achieved during the performance of the contract	• The Draft Technical Progress Report shall be submitted 75 calendar days before the end of the PoP and the Final Technical Progress Report on or before the completion date of the PoP • COR will provide feedback on draft report within 15 calendar days of receipt, which the Contractor shall consider incorporating into the Final Report
02.5 (Draft) 02.6 (Final)	Draft and Final Study Reports, Clinical and Non-Clinical	Contractor shall provide Draft and Final Clinical/Non-Clinical Study Reports to BARDA for review and comment.	• Draft report due within 45 calendar days after completion of analysis and at least 15 business days prior to submission to FDA • Subcontractor prepared reports received by the Contractor shall be submitted to the COR and CO for review and comment no later than 5 business days after receipt by Contractor • The Government will provide written comments to the Draft Report for Clinical / Non-Clinical Study reports within 15 business days after the submission • Final report due 30 calendar days after receiving comments on the Draft Final

			Report for Clinical and Non-Clinical Studies; If corrective action is recommended, Contractor must address all concerns raised by BARDA in writing • Contractor shall consider revising reports to address BARDA's recommendations prior to FDA submission
02.7	FDA Manufacturing Reports	At BARDA's request, Contractor shall provide Manufacturing Reports to BARDA for review and comment prior to submission to FDA The COR and CO reserve the right to request within the PoP a non-proprietary Manufacturing Report for distribution within the USG	• Contractor will submit Manufacturing Reports at least 15 business days prior to FDA submission • The Government will provide written comments to the manufacturing report within 15 business days after the submission • If corrective action is recommended, Contractor must address all concerns raised by BARDA in writing • Contractor shall consider revising reports to address BARDA's concerns and/or recommendations prior to FDA submission
02.8	Product Development Source Material and Manufacturing Report	The Contractor shall submit a detailed spreadsheet regarding critical project materials that are sourced from a location other than the United States, sources, and manufacturing sites, including but not limited to: physical locations of sources of raw and processed material by type of material; location and nature of work performed at manufacturing sites; and location and nature of non-clinical and clinical study sites.	• Contractor will submit Product Development Source Material Report o Within month of contract award o Within 30 days of substantive changes are made to sources and/or materials o Or on the 6th month contract anniversary. • The Government will provide written comments to the Product Development Source Material and Manufacturing Report within 15 business days after the submission • If corrective action is recommended, Contractor must address all concerns raised by BARDA in writing
02.9	Contractor Locations	The contractor shall submit detailed data regarding locations where work will be performed under this contract, including addresses, points of contact, and work performed per location, to include sub-contractors.	Contractor will submit Work Locations Report: • Within 5 business days of contract award • Within 30 business days after a substantive location or capabilities change • Within 2 business days of a substantive change if the work performed supports medical countermeasure development that addresses a threat that has been declared a Public Health Emergency by the HHS Secretary or a Public Health Emergency of International Concern (PHEIC) by the WHO
02.10	Clinical Report during Active Enrollment Periods	The contractor shall submit detailed clinical reports during active clinical trial enrollment to include at a minimum number of subjects screened and enrolled, site activation status, safety reporting (SAEs), deviation reports and database management. Exact format TBD by COR and contractor.	Contractor shall submit Clinical Reports on a weekly basis starting when first patient is enrolled and ending when last patient is enrolled.

02.11	Study Protocols	The contractor shall submit draft and final nonclinical and clinical study protocols to CO and COR	Draft study protocols will be submitted to COR electronically prior to finalization. ○ BARDA will provide comments within 10 days of receipt of draft protocol ○ Contractor shall respond in writing to BARDA comments and recommendations prior to finalization of protocol. Final study protocols will be submitted to COR electronically no later than 10 business days prior to FDA submission
02.12	Final Data Submission Package	Contractor must submit a data package consisting of all raw data produced under this contract. Data may be used by BARDA for analysis, evaluation, shared with other agencies, or shared outside of the government consistent with FAR 52.227-14. This submission package must be delivered in a non-proprietary format. If clinical trial data is included, that data must be provided consistent with applicable privacy laws to protect personally identifiable information (PII).	Contractor will submit at least 15 days prior to contract end date. Partial data-sets may also be requested for delivery prior to submission of the Final Data Submission Package.
02.13	Supplemental Technical Documents, Raw Data, or Data Analysis	Upon request and also as part of deliverables the Contractor shall provide raw data, data analysis, or data report to BARDA.	Contractor shall provide the Technical Documents upon request from the CO or COR
03	**Audits**		
03.1	BARDA Audit	Contractor shall accommodate periodic or ad hoc site visits by BARDA. If BARDA, the Contractor, or other parties identifies any issues during an audit, the Contractor shall capture the issues, identify potential solutions, and provide a report to BARDA	• If issues are identified during the audit, Contractor shall submit a report to BARDA detailing the finding and corrective action(s) within 10 business days of the audit • COR and CO will review the report and provide a response to the Contractor with 10 business days • Once corrective action is completed, the Contractor will provide a final report to BARDA
03.2	FDA Audits	In the event of an FDA inspection that occurs in relation to this contract and for the product, or for any other FDA inspection that has the reasonable potential to impact the performance of this contract, the Contractor shall provide the USG with an exact copy (non-redacted) of the FDA Form 483 and the Establishment Inspection Report (EIR). The Contractor shall provide the COR and CO with copies of the plan for addressing areas of non-conformance to FDA regulations for GLP, GMP, or GCP guidelines as identified in the audit report, status	• Contractor shall notify CO and COR within 10 business days of a scheduled FDA audit or within 24 hours of an ad hoc site visit/audit if the FDA does not provide advanced notice • Contractor shall provide copies of any FDA audit report received from subcontractors that occur as a result of this contract or for this product within 1 business day of receiving correspondence from the FDA or third party • Within 10 business days of audit report, Contractor shall provide CO with a plan for

		updates during the plans execution and a copy of all final responses to the FDA. The Contractor shall also provide redacted copies of any FDA audits received from subcontractors that occur as a result of this contract or for this product. The Contractor shall make arrangements for BARDA representative(s) to be present during the final debrief by the regulatory inspector	addressing areas of nonconformance, if any are identified
03.3	QA Audits	BARDA reserves the right to participate in QA audits performed by the contractor. Upon completion of the audit/site visit the Contractor shall provide a report capturing the findings, results and next steps in proceeding with the subcontractor. If action is requested of the subcontractor, detailed concerns for addressing areas of non-conformance to FDA regulations for GLP, GMP, or GCP guidelines, as identified in the audit report, must be provided to BARDA. The Contractor shall provide responses from the subcontractors to address these concerns and plans for corrective action	• Contractor shall notify CO and COR a minimum of 10 business days in advance of upcoming, audits/site visits of subcontractors • Contractor shall notify the COR and CO within 5 business days of report completion. • COR and CO will review the report and provide a response to the Contractor with 10 business days
03.4	Risk Management Plan (RMP)	The Contractor shall provide an RMP that outlines the impacts of each risk in relation to the cost, schedule, and performance objectives. The plan shall include risk mitigation strategies. Each risk mitigation strategy will capture how the corrective action will reduce impacts on cost, schedule and performance	• A Draft is due 90 business days within contract award; updates to the RMP are due concurrent with Monthly Technical Progress Reports. The contractor may choose to notify the government up to two times every three months if there are no changes from the prior submission, and not submit an update • BARDA will provide Contractor with a list of concerns in response plan submitted • Contractor must address, in writing, all concerns raised by BARDA within 20 business days of Contractor's receipt of BARDA's concerns
03.5	Integrated Master Schedule (IMS)	The contractor shall provide an IMS that illustrates project tasks, dependencies, durations throughout the period of performance, and milestones (GO/NO-GO). The IMS must map to the WBS, and provide baseline, and actual or forecast dates for completion of tasks	• The IMS is to be submitted in both PDF and Microsoft Project Form to the COR • The first Draft of the IMS is due 30 business within contract award • The Government will request revisions within 10 business days, at which point the schedule baseline for the period of performance will be set • Thereafter an updated IMS is due concurrent with Monthly Technical Progress Reports
03.6	Deviation Notification and Mitigation Strategy	Process for changing IMS activities associated with cost and schedule as baselined. Contractor shall notify BARDA of significant proposed changes the IMS defined as increases in cost above 5% or schedule slippage of more than 30 days, which would require a PoP extension. Contractor	• Due at least 10 business days prior to the Contractor anticipating the need to implement changes

		shall provide a high level management strategy for risk mitigation	
03.7	Incident Report	Contractor shall communicate to BARDA and document all critical programmatic concerns, issues, or probable risks that have or are likely to significantly impact project schedule and/or cost and/or performance. "Significant" is frequently defined as a 10% or greater cost or schedule variance within a control account, but should be confirmed in consultation with the COR. Incidents that present liability to the project even without cost/schedule impact, such as breach of GCP during a clinical study, must also be reported	•Due within 48 hours of activity or incident or within 24 hours for a security activity or incident •Email or telephone with written follow-up to COR and CO •Additional updates due to COR and CO within 48 hours of additional developments •Contractor shall submit within 5 business days a Corrective Action Plan (if deemed necessary by either party) to address any potential issues •If corrective action is deemed necessary, Contractor must address in writing, its consideration of concerns raised by BARDA within 5 business days of receiving such concerns
09	**Advanced R&D Products**		
09.1	Technical Documents	Upon request, Contractor shall provide CO and COR with deliverables from the following contract funded activities: quality agreements between contractors and sub-contractors, process Development Reports, Assay Qualification Plan/Report, Assay Validation Plan/Report, Assay Technology Transfer Report, Batch Records, SOPs, Master Production Records, Certificate of Analysis, Clinical Studies Data or Reports. The CO and COR reserve the right to request within the PoP a non-proprietary technical document for distribution within the Government	•Contractor shall provide technical document within 10 business days of CO or COR request. Contractor can request additional time on an as needed basis •If corrective action is recommended, the Contractor must address, in writing, concerns raised by BARDA in writing
09.2	Animal Model or Other Technology Transfer Package	Contractor shall provide Animal Model or Other Technology Transfer Package containing relevant methodology and data sufficient to enable other practitioners in the field to successfully replicate experimental conditions developed and tested with BARDA support	•Contractor shall provide a draft package within 20 business days of COR or CO request •Contractor shall revise the package to address BARDA's concerns, recommendations and/or requests for additional detail
09.3	Raw Data or Data Analysis	Contractor shall provide raw data or data analysis to BARDA upon request	•Contractor shall provide raw data or data analysis to CO and COR within 20 business days of request
09.4	Publications	Any manuscript or scientific meeting abstract containing data generated under this contract must be submitted to BARDA for review prior to submission. Acknowledgment of BARDA funding must be included as noted in contract articles H.9 and H.24	• Contractor must submit all manuscript or scientific meeting abstract to PO and CO prior to submission/presentation by 30 business days for manuscripts and 15 business days for abstracts or posters • Contractor must address in writing all concerns raised by BARDA in writing • Final submissions shall be submitted to BARDA concurrently or no later than one (1) calendar day of its submission
10	**Regulatory Documents**		

10.1	FDA Correspondence	The Contractor shall memorialize any correspondence between Contractor and FDA and submit to BARDA	• Contractor shall provide copies of any FDA correspondence within 2 business days of correspondence
10.2	FDA Submissions	The Contractor shall provide BARDA the opportunity to review and comment upon all draft submissions before submission to the FDA. Contractor shall provide BARDA with an electronic copy of the final FDA submission. All documents shall be duly marked as either "Draft" or "Final"	• Contractor shall submit draft FDA submissions to BARDA at least 15 business days prior to FDA submission • BARDA will provide feedback to Contractor within 10 business days of receipt • The Contractor must address, in writing, its consideration of all concerns raised by BARDA prior to FDA submission • Final FDA submissions shall be submitted to BARDA concurrently or no later than 1 calendar day of submission
11	Press Releases	Contractor agrees to accurately and factually represent the work conducted under this contract in all press releases	• Contractor shall ensure that the CO has received and approved an advanced copy of any press release to this contract not less than 5 business days prior to the issuance of the press release • If corrective action is required, the Contractor agrees to accurately and factually represent the work conducted under this contract in all press releases • Any final press releases shall be submitted to BARDA no later than one (1) calendar day prior to its release

2. Detailed Description of Select Contract Deliverables

A. Monthly and Annual Progress Reports

In addition to those reports required by the other terms of this contract, the Contractor shall prepare and submit the following reports in the manner stated below and in accordance with this Article F of this contract, and in the Statement of Work, attached to this contract as Attachment 1 (SECTION J-List of Attachments).

i. Monthly Progress Report

This report shall include a description of the activities during the reporting period, and the activities planned for the ensuing reporting period. The first reporting period consists of the first full month of performance plus any fractional part of the initial month. Thereafter, the reporting period shall consist of each calendar month.

The Contractor shall submit a Monthly Progress Report according to the dates set forth in the summary table ("Summary of Contract Deliverables") under this article. The progress report shall conform to the requirements set forth in the DELIVERIES Article in SECTION F of this contract.

The format should include:

- A cover page that includes the contract number and title; the type of report and period that it covers; the Contractor's name, address, telephone number, fax number, and e-mail address; and the date of submission;
- SECTION I – EXECUTIVE SUMMARY
- SECTION II - PROGRESS
- SECTION II Part A: OVERALL PROGRESS - A description of overall progress.
- SECTION II Part B: MANAGEMENT AND ADMINISTRATIVE UPDATE - A description of all meetings, conference calls, etc. that have taken place during the reporting period. Include progress on administration and management issues (e.g., evaluating, and managing subcontractor performance, and personnel changes).
- SECTION II Part C: TECHNICAL PROGRESS - For each activity related to Gantt chart, document the results of work completed and cost incurred during the period covered in relation to proposed progress, effort and budget. The report shall be in sufficient detail to explain comprehensively the results achieved. The description shall include pertinent data and/or graphs in sufficient detail to explain any significant results achieved and preliminary conclusions resulting from analysis and scientific evaluation of data accumulated to

date under the contract. The report shall include a description of problems encountered and proposed corrective action; differences between planned and actual progress, why the differences have occurred and what corrective actions are planned; preliminary conclusions resulting from analysis and scientific evaluation of data accumulated to date under the project.

- SECTION II Part D: PROPOSED WORK - A summary of work proposed related to Gantt chart for thenext reporting period and preprints/reprints of papers and abstracts.
- SECTION III: Estimated and Actual Expenses.
  a. This section of the report shall contain a narrative or table detailing whether there is a significant discrepancy (>10%) at this time between the % of work completed and the cumulative costs incurred to date. Monthly and actual expenses should be broken down to the appropriate WBS level.
  b. This section of the report should also contain estimates for the Subcontractors' expenses from the previous month if the Subcontractor did not submit a bill in the previous month. If the subcontractor(s) was not working or did not incur any costs in the previous month, then a statement to this effect should be included in this report for those respective subcontractors.

A Monthly Progress Report will not be required in the same month that the Annual Progress Report is submitted.

ii. Annual Progress Report

This report shall include a summation of the results of the entire contract work for the period covered. Monthly Progress Reports shall not be submitted in the same month when an Annual Progress Report is due. Furthermore, an Annual Progress Report will not be required for the period when the Final Report is due.

The first Annual Progress Report shall be submitted in accordance with the date set forth in the table ("Summary of Contract Deliverables") under ARTICLE F.2. of this contract. The progress report shall conform to the requirements set forth in the DELIVERIES Article in SECTION F of this contract.

Each Annual Progress Report shall include:

- A Cover page that includes the contract number and title; the type of report and period that it covers; the Contractor's name, address, telephone number, fax number, and email address; and the date of submission;
- SECTION I: EXECUTIVE SUMMARY - A brief overview of the work completed, and the major accomplishments achieved during the reporting period.
- SECTION II: PROGRESS
- SECTION II Part A: OVERALL PROGRESS - A description of overall progress.
- SECTION II Part B: MANAGEMENT AND ADMINISTRATIVE UPDATE - A high level summary of critical meetings, etc. that have taken place during the reporting period. Include progress on administration and management to critical factors of the project (e.g. regulatory compliance audits and key personnel changes).
- SECTION II Part C: TECHNICAL PROGRESS - A detailed description of the work performed structured to follow the activities and decision gates outlined at the Integrated Baseline Review and as described in the Integrated Master Plan. The Report should include a description of any problems (technical or financial) that occurred or were identified during the reporting period, and how these problems were resolved.
- SECTION II Part D: PROPOSED WORK - A summary of work proposed for the next year period to include an updated Gantt Chart.
- SECTION III: Estimated and Actual Expenses.
  a. This section of the report shall contain a narrative or table detailing whether there were discrepancies between estimated and actual expenses over the past year. Actual expenses should be broken down to the appropriate WBS level. This section of the report should also contain estimates for outstanding costs for the previous year which may have been incurred, but not yet billed.

Contractor also should include the following in the Annual Progress Report:

1. Copies of manuscripts (published and unpublished), abstracts, and any protocols or methods developed specifically under the contract during the reporting period; and
2. A summary of any Subject Inventions per the requirements under FAR Clause 52.227-11.

iii. Draft Final Report and Final Report

These reports are to include a summation of the work performed and results obtained for the entire contract period of performance. This report shall be in sufficient detail to describe comprehensively the results achieved. The Draft Final Report and Final Report shall be submitted in accordance with the DELIVERIES Article in SECTION F of the contract. An Annual Progress Report will not be required for the period when the Final Report is due. The Draft Final

Report and the Final Report shall be submitted in accordance with the dates set forth in the table ("Summary of Contract Deliverables") under ARTICLE F.2. of this contract. The report shall conform to the following format:

1. Cover page to include the contract number, contract title, performance period covered, Contractor's name and address, telephone number, fax number, email address and submission date.

2. SECTION I: EXECUTIVE SUMMARY - Summarize the purpose and scope of the contract effort including a summary of the major accomplishments relative to the specific activities set forth in the Statement of Work.

3. SECTION II: RESULTS - A detailed description of the work performed related to WBS and Gantt chart, the results obtained, and the impact of the results on the scientific and/or public health community including a listing of all manuscripts (published and in preparation) and abstracts presented during the entire period of performance and a summary of all inventions.

Draft Final Report: The Contractor is required to submit the Draft Final Report to the Contracting Officer's Representative and Contracting Officer. The Contracting Officer's Representative and Contracting Officer will review the Draft Final Report and provide the Contractor with comments in accordance with the dates set forth in ARTICLE F.2. of this contract.

Final Report: The Contractor will deliver the final version of the Final Report on or before the completion date of the contract. The final version shall include or address the COR's and CO's written comments on the draft report. Final Report shall be submitted on or before the completion date of the contract.

iv. Summary of Salient Results

The Contractor shall submit, with the Final Report, a summary (not to exceed 200 words) of salient results achieved during the performance of the contract.

v. Audit Reports

Within thirty (30) calendar days of an audit related to conformance to FDA regulations and guidance, including adherence to GLP, GMP, GCP guidelines, the Contractor shall provide copies of the audit report (so long as received from the FDA) and a plan for addressing areas of nonconformance to FDA regulations and guidelines for GLP, GMP, or GCP guidelines as identified in the final audit report.

vi. Other Technical Reports

1. Draft Report for Clinical and Non-Clinical Studies and Final Report for Clinical and Non-Clinical Studies

- The clinical trial reports shall follow the format of International Conference on Harmonization document ICH E3 "Guideline for Industry on Structure and Content of Clinical Study Reports"
- Draft Final Report for Clinical and Non-Clinical Studies funded by this contract will be submitted to the Contracting Officer's Representative and Contracting Officer (CO) for review and comment within the time frames set forth in the table ("Summary of Contract Deliverables") under ARTICLE F.2.
- Subcontractor prepared reports received by the Contractor shall be submitted to the Contracting Officer's Representative and Contracting Officer (CO) for review and comment as set forth by the table in this Article. Contractor shall consider revising reports to address BARDA's recommendations prior to FDA submission.
- The Government shall provide written comments to the Draft Final Report for Clinical and Non-Clinical Studies in accordance with the dates set forth by the table in this Article.
- The comprehensive Final Report for Clinical and Non-Clinical Studies will be submitted to the Contracting Officer and the Contracting Officer's Representative set forth by the table in this Article.

2. Supplemental Technical Documents

Upon request, Contractor shall provide CO and COR with the following contract funded documents as specified below but not limited to: Process Development Reports; Assay Qualification Plan/Report, Assay Validation Plan/Report, Assay Technology Transfer Report, Batch Records, Contractor/Subcontractor Standard Operating Procedures (SOP's), Master Production Records, Certificate of Analysis, Clinical Studies Data or Reports. The CO and COR reserve the right to request within the Period of Performance a non-proprietary technical document for distribution within the USG. Contractor shall provide technical document within 10 business days of CO or COR request. Contractor can request additional time on an as needed basis. If edits are recommended, the Contractor must address, in writing, concerns raised by BARDA.

B. Deliverables Arising from FDA Correspondence

i. FDA Meetings

The Contractor shall forward the dates and times of any meeting with the FDA to BARDA and make arrangements for appropriate BARDA staff to attend the FDA meetings. BARDA staff shall include up to a maximum of four people.

- Contractor shall notify BARDA of upcoming FDA meeting within 24 hours of scheduling Type A, B or C meetings OR within 24 hours of meeting occurrence for ad hoc meetings.
- The Contractor shall forward initial Contractor and FDA-issued draft minutes and final minutes of any meeting with the FDA to BARDA within 5 business days of receipt. All documents shall be duly marked as either "Draft" or "Final."

ii. FDA Submissions

The Contractor shall provide BARDA all documents submitted to the FDA.
Contractor shall provide BARDA with an electronic copy of the final FDA submission. All documents shall be duly marked as either "Draft" or "Final."

- When draft documents are submitted for BARDA review, BARDA will provide feedback to Contractor within 3 business days of receipt.
- When BARDA reviews draft documents, the Contractor shall revise their documents to address BARDA's written concerns and/or recommendations prior to FDA submission.
- Final FDA submissions shall be submitted to BARDA concurrently or no later than 1 calendar day of their submission to FDA.

iii. FDA Audits

In the event of an FDA inspection which occurs as a result of this contract and for the product, or for any other FDA inspection that has the reasonable potential to impact the performance of this contract, the Contractor shall provide the USG with an exact copy (non-redacted) of the FDA Form 483 and the Establishment Inspection Report (EIR) within five (5) business days after the Contractors receipt of those documents. The Contractor shall provide the COR and CO with copies of the plan for addressing areas of non-conformance to FDA regulations for GLP, GMP, or GCP guidelines as identified in the audit report, status updates during the plans execution and a copy of all final responses to the FDA. The Contractor shall also provide redacted copies of any FDA audits received from subcontractors that occur as a result of this contract or for this product. The Contractor shall make arrangements for BARDA representative(s) to be present during the final debrief by the regulatory inspector.

- Contractor shall notify CO and COR within 10 business days of a scheduled FDA audit or within 24 hours of an ad hoc site visit/audit if the FDA does not provide advanced notice.
- Contractor shall provide copies of any FDA audit report received from subcontractors that occur as a result of this contract or for this product within 5 business days of receiving correspondence from the FDA, Subcontractor, or third party.
- Within 10 business days of audit report, Contractor shall provide CO with a plan for addressing areas of nonconformance, if any are identified.

iv. Manufacturing Campaign Reports

Contractor shall provide Manufacturing Campaign Reports to BARDA for review and comment prior to submission to FDA.

The COR and CO reserve the right to request within the Period of Performance (PoP) a non-proprietary Manufacturing Campaign Report for distribution within the USG.

- Contractor will submit Manufacturing Campaign Reports at least 15 business days prior to FDA submission.
- If corrective action is recommended, Contractor shall address, in writing, the concerns raised by BARDA.
- Contractor shall revise the reports to address BARDA's concerns and/or recommendations prior to FDA submission.
- Final FDA submission shall be submitted to BARDA concurrently or no later than 1 business day after submission to the FDA.

v. Other FDA Correspondence

The Contractor shall memorialize any correspondence between Contractor and FDA and submit to BARDA. All documents shall be duly marked as either "Draft" or "Final." Contractor shall provide written summary of any FDA correspondence within 5 business days of correspondence.

i. Risk Management Plan

The Contractor shall provide a Risk Management Plan that outlines the impacts of each risk in relation to the cost, schedule, and performance objectives. The plan shall include risk mitigation strategies. Each risk mitigation strategy will capture how the corrective action will reduce impacts on cost, schedule and performance.

- Due within 90 days of contract award
- Contractor provides updated Risk Management Plan in Monthly Progress Report
- BARDA shall provide Contractor with a written list of concerns in response plan submitted
- Contractor must address, in writing, all concerns raised by BARDA within 20 business days ofContractor's receipt of BARDA's concerns.

3. Contract WBS Milestones/Deliverables and Technical Deliverables

Work Breakdown Structure (WBS), Go/No Go Program Stage Gates Gantt Chart, Integrated Master Schedule (IMS)

Work Breakdown Structure and Option Periods

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

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Integrated Program Gantt Chart
Gantt Chart of Moderna's Proposal "Development of an mRNA Vaccine mRNA vaccine"

[***]

Deliverables

The primary deliverable of this proposal is a licensed mRNA vaccine. In addition, the team, in partnership with BARDA, will also design a plan to enhance Moderna's ability to rapidly respond to a Coronavirus pandemic by leveraging our mRNA platform. Interim deliverables are presented below.

WBS	Title	Deliverable	[***]
1	**mRNA Vaccine Development**		
1.1	**Program Management**		
1.1.1	Program and Alliance Management	-Management Plans; Routine Reporting Deliverables	[***]
1.2	**Nonclinical Toxicology**		
1.2.2	**Safety**		
1.2.2.1	Development and Reproductive Toxicology	- Final Study Report	[***]
1.3	**Nonclinical**		
1.3.1	**Model Development (reserved)**		
1.3.1.2	NHP Efficacy Study	- Final Study Report	[***]
1.3.1.3	Mouse Efficacy Study	- Final Study Report	[***]
1.4	**Clinical**		
1.4.2	**Phase 2**		
1.4.2.1	Phase 2 Safety and Immunogenicity Study	- Clinical Study Protocol	[***]
		- Final Clinical Study Report	[***]
1.4.3	**Phase 3**		
1.4.3.1	Phase 3 Efficacy or Safety and Immunogenicity	- Clinical Study Protocol	[***]
		- Final Clinical Study Report	[***]
1.4.3.2	Phase 3 Lot-to-Lot	- Clinical Study Protocol	[***]
		- Final Clinical Study Report	[***]
1.4.3.3	Phase 3 Adolescents	- Clinical Study Protocol	[***]
		- Final Clinical Study Report	[***]
1.5	**Regulatory**		
1.5.1	**IND**		
1.5.1.1	IND Filing	- NA	
1.5.1.2	IND Maintenance	- Record of FDA Communications	[***]
1.5.2	**BLA**		[***]
1.5.2.1	BLA Submission	- NA	
1.6	**CMC**		
1.6.3	**Pilot Scale Manufacturing**		
1.6.3.2	CTM Manufacture for P201	- CoA for Clinical Lots	[***]
1.6.3.4	CTM Manufacture for P301	- CoA for Clinical Lots	[***]
1.6.3.6	CTM Manufacture for P302/P303	- CoA for Clinical Lots	[***]

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G. CONTRACT ADMINISTRATION

G.1 Contracting Officer

The Contracting Officer (CO) is the only individual who can legally commit the Government to the expenditure of public funds. No person other than the Contracting Officer can make any changes to the terms, conditions, general provisions or other stipulations of this Contract.

The Contracting Officer is the only individual with authority to act as agent of the Government under this Contract, with authority to (1) direct or negotiate any changes in the statement of work, (2) modify or extend the period of performance, (3) authorize reimbursement to the Contractor for any costs incurred during the performance of this Contract and/or (5) otherwise change any terms and conditions of this Contract.

No information, other than that which may be contained in an authorized modification to this contract duly issued by the Contracting Officer, which may be received from any person employed by the United States Government, or otherwise, shall be considered grounds for deviation from any stipulation of this contract.

Wendell Conyers – (202) 692-4784 – wendell.conyers@hhs.gov – Office No. 21K13
Supervisory Contract Specialist Division of Contracts Management & Acquisition (CMA)
Biomedical Advanced Research & Development Authority (BARDA)

G.2 Contracting Officer's Representative

As delegated by the CO, the Contracting Officer's Representative (COR) is responsible for: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) assisting the CO in interpreting the statement of work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections required by this contract; and (5) assisting in the resolution of technical problems encountered during performance.

Chuong Huynh – (202) 260-2177 – chuong.huynh@hhs.gov – Office No.
Project Officer / COR for Development Activities
Influenza and Emerging Infectious Diseases Division
Biomedical Advanced Research & Development Authority (BARDA)

G.3 Deliveries

All deliveries of physical documents, shall be addressed in the following format:

UPS/FedEx/USPS
U.S. Department of Health & Human Services *Insert Recipient's Name* HHS/ASPR/BARDA *Insert Office Number* – O'Neill House Office Building, 2nd Floor Washington, DC 20515 *Insert Recipient's Telephone Number*

G.4 Invoicing Instructions

Invoices for payment shall be submitted to the Contracting Officer and Contracting Officer's Representative, as one (1) hard copy and one (1) electronic copy addressed in the format indicated in G.3, shall follow the detailed invoicing instructions listed in Section J, and include an SF-1034.

CO	COR	Alternate COR	PSC
Wendell Conyers (Contracting Officer) HHS/ASPR/BARDA/CMA O'Neill House Office Building Room Number 21C06 Washington, DC 20515 Email: wnedell.conyers@hhs.gov	Chuong Huynh (COR HHS/ASPR/BARDA O'Neill House Office Building Room Number 24K24 Washington, DC 20515 TBD	TBD Alt COR HHS/ASPR/BARDA O'Neill House Office Building Room Number 24K13 Washington, D.C.20515 TBD	PSC_Invoices@psc.hhs.gov & "HHS e-Room" (shared access may be provided to

			the Contractor after award).

a. Contractor invoices/financial reports shall conform to the form, format, and content requirements of the instructions for Invoice/Financing requests and Contract Financial Reporting.

b. Monthly invoices must include the cumulative total expenses to date, adjusted (as applicable) to show any amounts suspended by the Government.

c. The Contractor agrees to immediately notify the CO in writing if there is an anticipated overrun (any amount) or unexpended balance (greater than 10%) of the estimated costs for the base period or any option period(s) (See estimated costs under Section B) and the reasons for the variance. These requirements are in addition to the specified requirements of FAR 52.232-20, Limitation of Cost that is incorporated by reference under Section I.1 which states;

Limitation of Cost (Apr 1984)

The parties estimate that performance of this contract, exclusive of any fee, will not cost the Government more than (1) the estimated cost specified in the Schedule or, (2) if this is a cost-sharing contract, the Government's share of the estimated cost specified in the Schedule. The Contractor agrees to use its best efforts to perform the work specified in the Schedule and all obligations under this contract within the estimated cost, which, if this is a cost-sharing contract, includes both the Government's and the Contractor's share of the cost.

The Contractor shall notify the Contracting Officer in writing whenever it has reason to believe that—

The costs the Contractor expects to incur under this contract in the next 60 days, when added to all costs previously incurred, will exceed 75 percent of the estimated cost specified in the Schedule; or

The total cost for the performance of this contract, exclusive of any fee, will be either greater or substantially less than had been previously estimated.

As part of the notification, the Contractor shall provide the Contracting Officer a revised estimate of the total cost of performing this contract. Except as required by other provisions of this contract, specifically citing and stated to be an exception to this clause—

- The Government is not obligated to reimburse the Contractor for costs incurred in excess of (i) the estimated cost specified in the Schedule or, (ii) if this is a cost-sharing contract, the estimated cost to the Government specified in the Schedule; and
- The Contractor is not obligated to continue performance under this contract (including actions under the Termination clause of this contract) or otherwise incur costs in excess of the estimated cost specified in the Schedule, until the Contracting Officer (i) notifies the Contractor in writing that the estimated cost has been increased and (ii) provides a revised estimated total cost of performing this contract. If this is a cost-sharing contract, the increase shall be allocated in accordance with the formula specified in the Schedule.
- No notice, communication, or representation in any form other than that specified in paragraph (d)(2) of this clause, or from any person other than the Contracting Officer, shall affect this contract's estimated cost to the Government. In the absence of the specified notice, the Government is not obligated to reimburse the Contractor for any costs in excess of the estimated cost or, if this is a cost-sharing contract, for any costs in excess of the estimated cost to the Government specified in the Schedule, whether those excess costs were incurred during the course of the contract or as a result of termination.
- If the estimated cost specified in the Schedule is increased, any costs the Contractor incurs before the increase that are in excess of the previously estimated cost shall be allowable to the same extent as if incurred afterward, unless the Contracting Officer issues a termination or other notice directing that the increase is solely to cover termination or other specified expenses.
- Change orders shall not be considered an authorization to exceed the estimated cost to the Government specified in the Schedule, unless they contain a statement increasing the estimated cost.
- If this contract is terminated or the estimated cost is not increased, the Government and the Contractor shall negotiate an equitable distribution of all property produced or purchased under the contract, based upon the share of costs incurred by each.

d. The Contractor shall submit an electronic copy of the payment request to the approving official instead of a paper copy. The payment request shall be transmitted as an attachment via e-mail to the address listed above in one of the following formats: MSWord, MS Excel, or Adobe Portable Document Format (PDF). Only one payment request shall be submitted per e-mail and the subject line of the e-mail shall include the Contractor's name, contract number, and unique invoice number.

e. An electronic copy of the payment request shall be uploaded into the designated eRoom (as defined in Section F.3

Electronic Submission) and an e-mail notification of the upload will be provided to the CO and COR.

f. All invoice submissions shall be in accordance with FAR 52.232-25, Prompt Payment (Oct 2008).
g. Invoices - Cost and Personnel Reporting, and Variances from the Negotiated Budget.

h. Invoices - Cost and Personnel Reporting, and Variances from the Negotiated Budget.

The Contractor agrees to provide a detailed breakdown on invoices of the following cost categories:

1. Direct Labor - List individuals by name, title/position, hourly/annual rate, level of effort (actual hours or % of effort), and amount claimed.
2. Fringe Benefits - Cite rate and amount
3. Overhead - Cite rate and amount
4. Materials & Supplies - Include detailed breakdown when total amount is over $100,000
5. Travel - Identify travelers, dates, destination, purpose of trip, and total breaking out amounts for transportation (plane, car, etc.), lodging, M&IE. Cite COA, if appropriate. List separately, domestic travel, general scientific meeting travel, and foreign travel.
6. Consultant Fees - Identify individuals, amounts and activities. Cite appropriate COA
7. Subcontracts - Attach subcontractor invoice(s). Cite appropriate COA
8. Equipment - Cite authorization and amount. Cite appropriate COA
9. Other Direct Costs - Include detailed breakdown when total amount is over $100,000.
10. G&A - Cite rate and amount.
11. Total Cost (and applicable cost-shared ratio)
12. Fixed Fee (if applicable)
13. Total Cost Plus Fixed Fee

Monthly invoices must include the cumulative total expenses to date, adjusted (as applicable) to show any amounts suspended by the USG. Nothing in this section discharges the contractor's responsibility to comply with any applicable FAR Parts 30 or 31 clauses' relating to cost reimbursement subcontracts. In order to verify allowability, further breakdown of costs may be requested at the USG's discretion. The Contractor shall subcontract with Firm Fixed Price Contracts to the maximum extent practicable.

Additional instructions and an invoice template are provided in Section J-List of Attachments, Invoice/Financing Request Instructions and Contract Financial Reporting Instructions for Cost- Reimbursement Contracts. All invoices must be signed by a representative of the contractor authorized to certify listed charges are accurate and comply with government regulations. Invoices shall be signed and submitted electronically (in accordance with Section F.3 Electronic Submission).

If applicable, the Contractor shall convert any foreign currency amount(s) in the monthly invoice to U.S. dollars each month, on the 1st of the month, using the foreign exchange rate index published on www.federalreserve.gov. Payment of invoices is subject to the U.S. dollar limits within the Total Costs of CLIN 0001 and 0002 in Section B of the contract.

The Government shall use electronic funds transfer to the maximum extent possible when making payments under this contract. FAR 52.232-33, Payment by Electronic Funds Transfer–System for Award Management, in Section I requires the Contractor to designate in writing a financial institution for receipt of electronic funds transfer payments.

The electronic version of the invoice can be submitted via e-mail or uploaded through HHS' eRoom (shared access may be provided to the Contractor after award).

The Government may request additional information (timecards, receipts, etc.) to support costs claimed in the Contractor's invoices. Incomplete invoices may be suspended by the Contracting Officer if the Contractor's claimed costs cannot be substantiated.

G.5 REIMBURSEMENT OF COST

The Government shall reimburse the Contractor the cost determined by the Contracting Officer to be allowable (hereinafter referred to as allowable cost) in accordance with FAR 52.216-7, Allowable Cost and Payment incorporated by reference in Section I, Contract Clauses, of this contract, and FAR Subpart 31.2. Examples of allowable costs include, but are not limited to, the following:

a) All direct materials and supplies that are used in performing the work provided for under the contract, including those purchased for subcontracts and purchase orders.

b) All direct labor, including supervisory, that is properly chargeable directly to the contract, plus fringe benefits.

c) All other items of cost budgeted for and accepted in the negotiation of this basic contract or modifications thereto.

d) Travel costs including per diem or actual subsistence for personnel while in an actual travel status in direct performance of the work and services required under this contract subject to the following:

(i) Air travel shall be by the most direct route using "air coach" or "air tourist" (less than first class or business class) unless it is clearly unreasonable or impractical (e.g., not available for reasons other than avoidable delay in making reservations, would require circuitous routing or entail additional expense offsetting the savings on fare, or would not make necessary connections).

(ii) Rail travel shall be by the most direct route, first class with lower berth or nearest equivalent.

(iii) Costs incurred for lodging, meals, and incidental expenses shall be considered reasonable and allowable to the extent that they do not exceed on a daily basis the per diem rates set forth in the Federal Travel Regulation (FTR).

(iv) Travel via privately owned automobile shall be reimbursed at not more than the current General Services Administration (GSA) FTR established mileage rate.

G.6 Providing Accelerated Payment to Small Business Subcontractors, FAR 52.232-40 (Dec. 2013)

(a) Upon receipt of accelerated payments from the Government, the Contractor shall make accelerated payments to its small business subcontractors under this contract, to the maximum extent practicable and prior to when such payment is otherwise required under the applicable contract or subcontract, after receipt of a proper invoice and all other required documentation from the small business subcontractor.
(b) The acceleration of payments under this clause does not provide any new rights under the prompt Payment Act.
(c) Include the substance of this clause, include this paragraph c, in all subcontracts with small business concerns, including subcontracts with small business concerns for the acquisition of commercial items.

G.7 Contract Communication/Correspondence

The Contractor shall identify all correspondence, reports, and other data pertinent to this contract by imprinting thereon the contract number from Page 1 of the contract.

[***]

3. In accordance with FAR Part 5.216-7(d), the contractor shall submit an adequate final indirect cost rates proposal to the contracting officer within the 6-months period following the end of its fiscal years during the period of contract performance

G.8 Post-Award Evaluation of Contractor Performance

(a) *Purpose:* In accordance with FAR 42.1502(a), past performance evaluations shall be prepared at least annually and at the time the work under a contract or order is completed, via CPARS, the Government-wide evaluation tool (www.cpars.gov).

(b) *Evaluators*: The performance evaluation will be completed jointly by the Contracting Officer's Representative and the Contracting Officer.

(c) *Performance Evaluation Factors*: Per FAR 42.1503(b)(2), evaluation factors for each assessment shall include, at a minimum: technical (quality of product or service); cost control; schedule/timeliness; management and business relations; small business subcontracting; other (as applicable).

(d) *Contractor Review*: A copy of the evaluation will be electronically sent to the Contractor as soon as practicable after completion of the evaluation. The Contractor shall submit comments, rebutting statements, or additional information to the Contracting Officer within 14 calendar days after receipt of the evaluation.

(e) *Resolving Disagreements between the Government and the Contractor*: Disagreements between the parties regarding the evaluation will be reviewed at a level above the Contracting Officer. The ultimate conclusion on the performance evaluation is a decision of the contracting agency. Copies of the evaluation, Contractor's response, and review comments, if any, will be retained as part of the evaluation.

(f) *Release of Contractor Performance Evaluation Information*: The completed evaluation will not be released to other than Government personnel and the Contractor whose performance is being evaluated. Disclosure of such information could cause harm both to the commercial interest of the Government and to the competitive position of the Contractor being evaluated, as well as impede the efficiency of Government operations.

(g) *Source Selection Information*: Departments and agencies may share past performance information with other Government departments and agencies when requested to support future award decisions. The information may be provided through interview and/or by sending the evaluation and comment document to the requesting source selection official.

(h) *Retention Period*: The agency will retain past performance information for a maximum period of 3 years after completion of contract performance for the purpose of providing source selection information for future contract awards.

H. SPECIAL CONTRACT REQUIREMENTS

H.1 Access and Disposition of Data

The Government shall have physical and electronic access to all documentation and data generated under this contract, including: all Contractor efforts; Subcontractor efforts; communications and correspondence with regulatory agencies and bodies to include all audit observations, inspection reports, meeting minutes, and all Contractor commitments and responses.

H.2 Interactions with the Food and Drug Administration (FDA)

The Contractor shall memorialize any interactions between the Contractor and the FDA, and submit documentation to the COR and CO. All documents shall be duly marked as either "Draft" or "Final."

H.2.1 FDA Correspondence

Contractor shall provide written summary of any FDA correspondence within five (5) business days of correspondence.

H.2.2 FDA Meetings

The Contractor shall forward the dates and times of any meeting with the FDA to the COR and CO, and make arrangements for appropriate BARDA staff to attend the FDA meetings. BARDA staff shall include up to a maximum of four people (COR, CO and up to 2 subject matter experts).

(1) Contractor shall notify the COR and CO of upcoming FDA meeting within 24 hours of scheduling Type A, B or C meetings, or within 24 hours of meeting occurrence for ad hoc meetings.
(2) The Contractor shall forward initial Contractor and FDA-issued draft and final minutes of any meeting with the FDA, to the COR and CO, within 2 business days of receipt. All documents shall be duly marked as either "Draft" or "Final."

H.2.3 FDA Pre-Submissions, Submissions, and Other Related Correspondence

The Contractor shall provide the COR and CO the opportunity to review and comment upon all draft submissions directly related to this contract before submission to the FDA. Contractor shall provide the COR and CO with an electronic copy of the final FDA submission. All documents shall be duly marked as either "Draft" or "Final".

(1) Contractor shall submit draft FDA submissions to the COR and CO at least 15 business days prior to FDA submission.
(2) The COR and CO will provide feedback to Contractor within 5 business days of receipt.
(3) If corrective action is recommended, the Contractor must address, in writing, its consideration of all concerns raised by the COR and CO.
(4) The Contractor shall consider revising their documents to address the COR and CO's concerns and/or recommendations prior to FDA submission.
(5) Final FDA submissions shall be submitted to the COR and CO concurrently or no later than 1 calendar day of its submission to FDA

H.2.4 FDA Audits

In the event of an FDA inspection which occurs as a result of this contract and for the product, or for any other FDA inspection that has the reasonable potential to impact the performance of this contract, the Contractor shall provide the USG with an exact copy (non-redacted) of the FDA Form 483 and the Establishment Inspection Report (EIR). The Contractor shall provide the COR and CO with copies of the plan for addressing areas of non-conformance to FDA regulations for GLP, GMP, or GCP guidelines as identified in the audit report, status updates during the plans execution and a copy of all final responses to the FDA. The Contractor shall also provide redacted copies of any FDA audits received from subcontractors that occur as a result of this contract or for this product. The Contractor shall make arrangements for BARDA representative(s) to be present during the final debrief by the regulatory inspector.

(1) Contractor shall notify CO and COR within 10 business days of a scheduled FDA audit or within 24 hours of an ad hoc site visit/audit if the FDA does not provide advanced notice.
(2) Contractor shall provide copies of any FDA audit report received from subcontractors that occur as a result of this contract or for this product within 5 business days of receiving correspondence from the FDA or third party.
(3) Within 10 business days of audit report, Contractor shall provide CO and COR with a plan for addressing areas of nonconformance, if any are identified.

H.3 Key Personnel

Pursuant to HHSAR 352.237-75 (Dec 2015), Key Personnel, any key personnel specified in this contract are considered to be essential to work performance. At least thirty (30) calendar days prior to the Contractor voluntarily diverting any of the specified individuals to other programs or contracts the Contractor shall notify the Contracting Officer and shall submit a justification for the diversion or replacement and a request to replace the individual. The request must identify the proposed replacement and provide an explanation of how the

replacement's skills, experience, and credentials meet or exceed the requirements of the contract (including, when applicable, Human Subjects Testing requirements). If the employee of the Contractor is terminated for cause or separates from the Contractor voluntarily with less than thirty (30) calendar-day notice, the Contractor shall provide the maximum notice practicable under the circumstances. The Contractor shall not divert, replace, or announce any such change to key personnel without the written consent of the Contracting Officer. The contract will be modified to add or delete key personnel as necessary to reflect the agreement of the parties. The following individuals are determined to be key personnel:

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H.3.1 Personnel Qualifications

The Contractor shall provide curriculum vitae (CV) for each individual identified as key personnel. The CV shall clearly describe the individual's knowledge, work experiences, registrations, and certifications, and applicable experience. The CV shall include a summary describing the individual's involvement in similar work.

H.4 Substitution of Key Personnel

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

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

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

H.5 Contracting Officer's Authorization (COA) for Subcontracting

The Contractor shall submit a Contracting Officer's Authorization (COA) approval request, to the Contracting Officer, for all subcontractors, consultants and equipment purchases proposed during the course of this contract. COAs for subcontractors and consultant agreements shall be submitting when the potential subcontract is expected to exceed $150,000; for equipment purchases, when the unit price per item is expected to exceed $25,000. Sufficient time shall be provided for the Government to fully assess the transaction proposed. The supporting documents shall include, but not be limited to:

1. Competition activities, as well as technical and cost/price evaluation activities performed, in the selection of the subcontractor(s);
2. The subcontractor's qualifications/capabilities statement as they pertain to the activities included in the proposed subcontract;
3. The subcontractor's willingness to perform under the Contractor (i.e. commitment letters/preliminary agreements), with a list of specific duties included in the proposed subcontract;
4. A complete subcontractor cost proposal or quote, in similar format as the Contractor's cost proposal.

H.6 No Personal Services or Inherently Governmental Function

Pursuant to FAR 37.1, no personal services shall be performed under this contract. All work requirements shall flow only from the COR to the Contractor's Project Manager. No Contractor employee will be directly supervised by the Government. All employee assignments, and daily work direction, shall be given by the applicable Contractor supervisor. If the Contractor believes any Government action or communication has been given that would create a personal services relationship between the Government and any Contractor employee, the Contractor shall promptly notify the Contracting Officer of this communication or action.

Pursuant to FAR 7.5, the Contractor shall not perform any inherently governmental actions under this contract. No Contractor employee shall hold him or herself out to be a Government employee, agent, or representative. No Contractor employee shall state orally or in writing at any time that he or she is acting on behalf of the Government. In all communications with third parties in connection with this contract, Contractor employees shall identify themselves as Contractor employees and specify the name of the company for which they work. In all communications with other Government Contractors in connection with this contract, the Contractor employee shall state that they have no authority to in any way change this contract and that if the other Contractor believes this communication to be a direction to change their contract, they shall notify the Contracting Officer for that contract and not carry out the direction until a clarification has been issued by the Contracting Officer.

The Contractor shall ensure that all of its employees working on this contract are informed of the substance of this article. Nothing in this article shall limit the Government's rights in any way under the other provisions of this contract, including those related to the Government's right to inspect and accept the services to be performed under this contract. The substance of this article shall be included in all subcontracts at any tier.

H.7 Acknowledgement of Federal Funding – Publication and Publicity

The Contractor shall acknowledge the support of the Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

"This project has been funded in whole or in part with Federal funds from the Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, under Contract No. 75A50120C00034."

Press Releases:

The Contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money: (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

H.8 352.270-4b, Protection of Human Subjects (Dec 2015)

(a) The Contractor agrees that the rights and welfare of human subjects involved in research under this contract shall be protected in accordance with 45 CFR part 46 and with the Contractor's current Federal-wide Assurance (FWA) on file with the Office for Human Research Protections (OHRP), Department of Health and Human Services. The Contractor further agrees to provide certification at least annually that the Institutional Review Board has reviewed and approved the procedures, which involve human subjects in accordance with 45 CFR part 46 and the Assurance of Compliance.

(b) The Contractor shall bear full responsibility for the performance of all work and services involving the use of human subjects under this contract and shall ensure that work is conducted in a proper manner and as safely as is feasible. The parties hereto agree that the Contractor retains the right to control and direct the performance of all work under this contract. Nothing in this contract shall create an agency or employee relationship between the Government and the Contractor, or any subcontractor, agent or employee of the Contractor, or any other person, organization, institution, or group of any kind whatsoever. The Contractor agrees that it has entered into this contract and will discharge its obligations, duties, and undertakings and the work pursuant thereto, whether requiring professional judgment or otherwise, as an independent Contractor without creating liability on the part of the Government for the acts of the Contractor or itsemployees.

(c) Contractors involving other agencies or institutions in activities considered to be engaged in research involving human subjects must ensure that such other agencies or institutions obtain their own FWA if they are routinely engaged in research involving human subjects or ensure that such agencies or institutions are covered by the Contractors' FWA via designation as agents of the institution or via individual investigator agreements (see OHRP website at: http://www.hhs.gov/ohrp/policy/guidanceonalternativetofwa.pdf).

(d) If at any time during the performance of this contract the Contractor is not in compliance with any of the requirements and or standards stated in paragraphs (a) and (b) above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. The Contracting Officer may communicate the notice of suspension by telephone with confirmation in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may, after consultation with OHRP, terminate this contract in whole or in part.

(End of clause)

H.9 HHSAR 352.270-5a, Notice to Offerors of Requirement for Compliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals (Dec 2015)

The Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (PHS Policy) establishes a number of requirements for research activities involving animals. Before awarding a contract to an offeror, the organization shall file, with the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), a written Animal Welfare Assurance (Assurance) which commits the organization to comply with the provisions of the PHS Policy, the Animal Welfare Act, and the Guide for the Care and Use of Laboratory Animals (National Academy Press, Washington, DC). In accordance with the PHS Policy, offerors must establish an Institutional Animal Care and Use Committee (IACUC), qualified through the experience and expertise of its members, to oversee the institution's animal program, facilities, and procedures. Offerors must provide verification of IACUC approval prior to receiving an award involving live vertebrate animals. No award involving the use of animals shall be made unless OLAW approves the Assurance and verification of IACUC approval for the proposed animal activities has been provided to the Contracting Officer. Prior to award, the Contracting Officer will notify Contractor(s) selected for projects involving live vertebrate animals of the Assurance and verification of IACUC approval requirement. The Contracting Officer will request that OLAW negotiate an acceptable Assurance with those Contractor(s) and request verification of IACUC approval. For further information, contact OLAW at NIH, 6705 Rockledge Drive, RKL1, Suite 360, MSC 7982 Bethesda, Maryland 20892-7982 (E-mail: olaw@od.nih.gov; Phone: 301–496–7163).

(End of provision)

H.10 HHSAR 352.270-5b, Care of Life Vertebrate Animals (Dec 2015)

(a) Before undertaking performance of any contract involving animal-related activities where the species is regulated by the United Sates Department of Agriculture (USDA), the Contractor shall register with the Secretary of Agriculture of the United States in accordance with 7 U.S.C. 2136 and 9 CFR 2.25 through 2.28. The Contractor shall furnish evidence of the registration to the Contracting Officer.

(b) The Contractor shall acquire vertebrate animals used in research from a dealer licensed by the Secretary of Agriculture under 7 U.S.C. 2133 and 9 CFR 2.1 2.11, or from a source that is exempt from licensing under those sections.

(c) The Contractor agrees that the care, use, and intended use of any live vertebrate animals in the performance of this contract shall conform with the Public Health Service (PHS) Policy on Humane Care of Use of Laboratory Animals (PHS Policy), the current Animal Welfare Assurance (Assurance), the Guide for the Care and Use of Laboratory Animals (National Academy Press, Washington, DC) and the pertinent laws and regulations of the United States Department of Agriculture (see 7 U.S.C. 2131 et seq. and 9 CFR subchapter A, Parts 1-4). In case of conflict between standards, the more stringent standard shall govern.

(d) If at any time during performance of this contract, the Contracting Officer determines, in consultation with the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), that the Contractor is not in compliance with any of the requirements and standards stated in paragraphs (a) through (c) above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may, in consultation with OLAW, NIH, terminate this contract in whole or in part, and the Contractor's name may be removed from the list of those contractors with Animal Welfare Assurances.

Note: The Contractor may request registration of its facility and a current listing of licensed dealers from the Regional Office of the Animal and Plant Health Inspection Service (APHIS), USDA, for the region in which its research facility is located. The location of the appropriate APHIS Regional Office, as well as information concerning this program may be obtained by contacting the Animal Care Staff, USDA/APHIS, 4700 River Road, Riverdale, Maryland 20737 (Email: ace@aphis.usda.gov; Web site: http://www.aphis.usda.gov/wps/portal/aphis/ourfocus/animalwelfare)

(End of clause)

H.11 Animal Welfare

All research involving live, vertebrate animals shall be conducted in accordance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy). The PHS Policy can be accessed at: http://grants1.nih.gov/grants/olaw/references/phspol.htm

H.12 Dissemination of False or Deliberately Misleading Information

The Contractor shall not use contract funds to disseminate information that is deliberately false or misleading.

H.13 Electronic Information and Technology Accessibility Notice

a. Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998 and the Architectural and Transportation Barriers Compliance Board Electronic and Information (EIT) Accessibility Standards (36 CFR part 1194), require that when Federal agencies develop, procure, maintain, or use electronic and information technology, Federal employees with disabilities have access to and use of information and data that is comparable to the access and use by Federal employees who are not individuals with disabilities, unless an undue burden would be imposed on the agency. Section 508 also requires that individuals with disabilities, who are members of the public seeking information or services from a Federal agency, have access to and use of information and data that is comparable to that provided to the public who are not individuals with disabilities, unless an undue burden would be imposed on the agency.

b. Accordingly, any Offeror responding to this solicitation must comply with established HHS EIT accessibility standards. Information about Section 508 is available at http://www.hhs.gov/web/508. The complete text of the Section 508 Final Provisions can be accessed at http://www.access-board.gov/sec508/standards.htm.

c. The Section 508 accessibility standards applicable to this solicitation are stated in the clause at 352.239-74, Electronic and Information Technology Accessibility.

In order to facilitate the Government's determination whether proposed EIT supplies meet applicable Section 508 accessibility standards, Offerors must submit an HHS Section 508 Product Assessment Template, in accordance with its completion instructions. The purpose of the template is to assist HHS acquisition and program officials in determining whether proposed EIT supplies conform to applicable Section 508 accessibility standards. The template allows
Offerors or developers to self-evaluate their supplies and document--in detail--whether they conform to a specific Section 508 accessibility standard, and any underway remediation efforts addressing conformance issues. Instructions for preparing the HHS Section 508 Evaluation Template are available under Section 508 policy on the HHS Web site http://hhs.gov/web/508.

In order to facilitate the Government's determination whether proposed EIT services meet applicable Section 508 accessibility standards, Offerors must provide enough information to assist the Government in determining that the EIT services conform to Section 508 accessibility standards, including any underway remediation efforts addressing conformance issues.

d. Respondents to this solicitation must identify any exception to Section 508 requirements. If a Offeror claims its supplies or services meet applicable Section 508 accessibility standards, and it is later determined by the Government, i.e., after award of a contract or order, that supplies or services delivered do not conform to the described accessibility standards, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its expense.

(End of provision)

H.14 Confidentiality of Information

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

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

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

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

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

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

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

H.15 Institutional Responsibility Regarding Investigator Conflicts of Interest

The Institution (includes any Contractor, public or private, excluding a Federal agency) shall comply with the requirements of 45 CFR Part 94, Responsible Prospective Contractors, which promotes objectivity in research by establishing standards to ensure that Investigators (defined as the project director or principal Investigator and any other person, regardless of title or position,

who is responsible for the design, conduct, or reporting of research funded under BARDA contracts, or proposed for such funding, which may include, for example, collaborators or consultants) will not be biased by any Investigator financial conflicts of interest. 45 CFR Part 94 is available at the following Web site: http://www.ecfr.gov/cgi-bin/textidx?c=ecfr&SID=0af84ca649a74846f102aaf664da1623&rgn=div5&view=text&node=45:1.0.1.1.51&idno=45

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

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

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

    Significant financial interests do not include the following:

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

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

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

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

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

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

g. Provide initial and ongoing FCOI reports to the Contracting Officer pursuant to Part 94.5(b).

h. Maintain records relating to all Investigator disclosures of financial interests and the Institution's review of, and response to, such disclosures, and all actions under the Institution's policy or retrospective review, if applicable, for at least 3 years from the date of final payment or, where applicable, for the other time periods specified in 48 CFR Part 4, subpart 4.7, Contract Records Retention.

i. Establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator compliance as appropriate.

j. Complete the certification in Section K - Representations, Certifications, and Other Statements of Contractors titled "Certification of Institutional Policy on Financial Conflicts of Interest".

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

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

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

H.16 Reporting Matters Involving Fraud, Waste and Abuse

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in BARDA funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is 1-800-HHS-TIPS (1-800-447-8477). All telephone calls will be handled confidentially. The e-mail address is Htips@os.dhhs.gov and the mailing address is:

Office of Inspector General
Department of Health and Human Services
TIPS HOTLINE
P.O. Box 23489
Washington, D.C. 20026

H.17 Prohibition on Contractor Involvement with Terrorist Activities

The Contractor acknowledges that U.S. Executive Orders and Laws, including but not limited to E.O. 13224 and Pub. L. 107-56, prohibit transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. It is the legal responsibility of the Contractor to ensure compliance with these Executive Orders and Laws. This clause must be included in all subcontracts issued under this contract.

H.18 FAR 52.227-14, Rights in Data – General (May 2014), Alternate II (December 2007)

As prescribed in FAR 27.409(b)(3), the following paragraph is inserted into (g)(3) of the basic clause:

(g)(3) Notwithstanding paragraph (g)(1) of this clause, the contract may identify and specify the delivery of limited rights data, or the Contracting Officer may require by written request the delivery of limited rights data that has been withheld or would otherwise be entitled to be withheld. If delivery of that data is required, the Contractor shall affix the following "Limited Rights Notice" to the data and the Government will treat the data, subject to the provisions of paragraphs (e) and (f) of this clause, in accordance with the notice:

Limited Rights Notice (Dec 2007)

(a) These data are submitted with limited rights under Government Contract No. 75A50120C00034 and subcontracts. These data may be reproduced and used by the Government with the express limitation that they will not, without written permission of the Contractor, be used for purposes of manufacture nor disclosed outside the Government; except that the Government may disclose

these data outside the Government for the following purposes, if any; provided that the Government makes such disclosure subject to prohibition against further use and disclosure:

(i) Use (except for manufacture) by support service.

(b) This notice shall be marked on any reproduction of these data, in whole or in part.

(End of notice)

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

PART II – CONTRACT CLAUSES

I. CONTRACT CLAUSES

I.1 52.252-2 Clauses Incorporated by Reference (Feb 1998)

This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this address: http://acquisition.gov/far/

The following FAR clauses, pertinent to Section I, are hereby incorporated by reference:

FAR Clause	Title	Date
52.202-1	Definitions	Nov 2013
52.203-3	Gratuities	Apr 1984
52.203-5	Covenant Against Contingent Fees	May 2014
52.203-6	Restrictions on Subcontractor Sales to the Government	Sep 2006
52.203-7	Anti-Kickback Procedures	May 2014
52.203-8	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity	May 2014
52.203-10	Price or Fee Adjustment for Illegal or Improper Activity	May 2014
52.203-12	Limitation on Payments to Influence Certain Federal Transactions	Oct 2010
52.203-13	Contractor Code of Business Ethics and Conduct	Oct 2015
52.203-14	Display of Hotline Poster(s)	Oct 2015
52.203-17	Contractor Employee Whistleblower Rights and Requirement To Inform Employees of Whistleblower Rights	Apr 2014
52.203-19	Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements	Jan 2017
52.204-1	Administrative Matters Provisions and Clauses	Dec 1989
52.204-4	Printed or Copied Double-Sided on Postconsumer Fiber Content Paper	May 2011
52.204-7	System for Award Management	Oct 2018
52.204-10	Reporting Executive Compensation and First-Tier Subcontract Awards	Oct 2018
52.204-13	System for Award Management Maintenance	Oct 2018
52.204-16	Commercial and Government Entity Code Reporting	Jul 2016
52.204-17	Ownership of Control or Offeror	Jul 2016
52.204-18	Commercial and Government Entity Code Maintenance	Jul 2016
52.204-19	Incorporation by Reference of Representations and Certifications	Dec 2014
52.204-23	Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities	Jul 2018
52.209-5	Certification Regarding Responsibility Matters	Oct 2015
52.209-6	Protecting the Government's Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment	Oct 2015
52.209-9	Updates of Publicly Available Information Regarding Responsibility Matters	Oct 2018
52.209-10	Prohibition on Contracting with Inverted Domestic Corporations	Nov 2015
52.210-1	Market Research	Apr 2011
52.215-2	Audit and Records – Negotiation	Oct 2010
52.215-8	Order of Precedence - Uniform Contract Format	Oct 1997
52.215-10	Price Reduction for Defective Cost or Pricing Data	Aug 2011
52.215-11	Price Reduction for Defective Certified Cost or Pricing Data—Modifications.	Aug 2011
52.215-12	Subcontractor Certified Cost or Pricing Data	Oct 2010

52.215-13	Subcontractor Certified Cost or Pricing Data—Modifications	Oct 2010
52.215-14	Integrity of Unit Prices (Over SAT)	Oct 2010
52.215-15	Pension Adjustments and Asset Reversions	Oct 2010
52.215-18	Reversion or Adjustment of Plans for Postretirement Benefits (PRB) other than Pensions	Jul 2005
52.215-19	Notification of Ownership Changes	Oct 1997
52.215-20	Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data)	Oct 2010
52.215-21	Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data -Modifications	Oct 2010
52.215-22	Limitations on Pass-Through Charges—Identification of Subcontract Effort	Oct 2009
52.215-23	Limitations on Pass-Through Charges	Oct 2009
52.216-7	Allowable Cost and Payment	Aug 2018
52.216-8	Fixed Fee	Jun 2011
52.217-8	Option to Extend Services *[within thirty (30) calendar days from contract expiration.]*	Nov 1999
52.219-8	Utilization of Small Business Concerns	Oct 2018
52.219-28	Post-Award Small Business Program Representation	July 2013
52.222-1	Notice to the Government of Labor Disputes	Feb 1997
52.222-2	Payment for Overtime Premiums *[*$0.00]*	July 1990
52.222-3	Convict Labor	Jun2003
52.222-21	Prohibition of Segregated Facilities	Apr 2015
52.222-24	Pre-award On-Site Equal Opportunity Compliance Evaluation	Feb 1999
52.222-26	Equal Opportunity	Sept 2016
52.222-35	Equal Opportunity for Veterans ($150,000 or more)	Oct 2015
52.222-36	Equal Opportunity for Workers with Disabilities	Jul 2014
52.222-37	Employment Reports on Veterans	Feb 2016
52.222-38	Compliance with Veterans' Employment Reporting Requirements	Feb 2016
52.222-40	Notification of Employee Rights Under the National Labor Relations Act	Dec 2010
52.222-50	Combating Trafficking in Persons	Jan 2019
52.222-54	Employment Eligibility Verification	Oct 2015
52.223-6	Drug-Free Workplace	May 2001
52.223-18	Encouraging Contractor Policy to Ban Text Messaging While Driving	Aug 2011
52.224-1	Privacy Act Notification	April 1984
52.224-2	Privacy Act	April 1984
52.224-3	Privacy Training	Jan 2017
52.225-13	Restrictions on Certain Foreign Purchases	Jun 2008
52.225-25	Prohibition on Contracting with Entities Engaging in Certain Activities or Transactions Relating to Iran—Representation and Certifications	Aug 2018
52.227-1	Authorization and Consent	Dec 2007
52.227-2	Notice and Assistance Regarding Patent and Copyright Infringement	Dec 2007
52.227-11	Patent Rights-Ownership by the Contractor	May 2014
52.227-14	Rights in Data – General	May 2014
52.227-14	Rights in Data – General, Alternate II (Dec 2007)	May 2014
52.228-7	Insurance – Liability to Third Persons	Mar 1996
52.232-9	Limitation on Withholding of Payments	Apr 1984

52.232-17	Interest	May 2014
52.232-20	Limitation of Cost	Apr 1984
52.232-23	Assignment of Claims	May 2014
52.232-25	Prompt Payment Alt I	Jan 2017
52.232-33	Payment by Electronic Funds Transfer--System for Award Management	Oct 2018
52.232-39	Unenforceability of Unauthorized Obligations	Jun 2013
52.232-40	Providing Accelerated Payments to Small Business Subcontractors	Dec 2013
52.233-1	Disputes	May 2014
52.233-3	Protest After Award, Alternate I (Jun 1985)	Aug 1996
52.233-4	Applicable Law for Breach of Contract Claim	Oct 2004
52.242-1	Notice of Intent to Disallow Costs	Apr 1984
52.242-3	Penalties for Unallowable Costs	May 2014
52.242-4	Certification of Final Indirect Costs	Jan 1997
52.242-13	Bankruptcy	Jul 1995
52.243-2	Changes—Cost-Reimbursement, Alternate I (Apr 1984)	Apr 1984
52.243-2	Changes—Cost-Reimbursement, Alternate V (Apr 1984)	Aug 1987
52.243-6	Change Order Accounting	Apr 1984
52.243-7	Notification of Changes	Jan 2017
52.244-2	Subcontracts, Alternate I (Jun 2007)	Oct 2010
52.244-5	Competition in Subcontracting	Dec 1996
52.244-6	Subcontracts for Commercial Items	Jan 2019
52.245-1	Government Property	Jan 2017
52.245-9	Use and Charges	Apr 2012
52.246-25	Limitation of Liability—Services	Feb 1997
52.249-6	Termination (Cost-Reimbursement)	May 2004
52.249-14	Excusable Delays	Apr 1984
52.253-1	Computer Generated Forms	Jan 1991

I.2 Department of Health and Human Services Acquisition Regulation (HHSAR) Clauses

Full text of HHSAR clauses may be accessed electronically at this address: http://www.hhs.gov/grants/contracts/contract-policies-regulations/hhsar

HHSAR Clause	Title	Date
352.203-70	Anti-Lobbying	Dec 2015
352.208-70	Printing and Duplication	Dec 2015
352.222-70	Contractor Cooperation in Equal Employment Opportunity Investigations	Dec 2015
352.223-70	Safety and Health	Dec 2015
352.224-71	Confidential Information	Dec 2016
352.227-70	Publications and Publicity	Dec 2015
352.231-70	Salary Rate Limitation	Dec 2015
352.233-71	Litigation and Claims	Dec 2015
352.237-75	Key Personnel	Dec 2015
352.239-74	Electronic and Information Technology Accessibility	Dec 2015
352.270-9	Non-discrimination for Conscience	Dec 2015

I.3 Additional Contract Clauses

I.3.1 Additional Federal Acquisition Regulation (FAR) Clauses in Full Text

52.217-9 Option to Extend the Term of the Contract (Mar 2000)

(a) The Government may extend the term of this contract by written notice to the Contractor within thirty (30) calendar days; provided that the Government gives the Contractor a preliminary written notice of its intent to extend at least thirty (30) days before the contract expires. The preliminary notice does not commit the Government to an extension.

(b) If the Government exercises this option, the extended contract shall be considered to include this option clause.

(c) The total duration of this contract, including the exercise of any options under this clause, shall not exceed five 5) years and six (6) months.

(End of Clause)

52.203-18 Prohibition on Contracting with Entities that Require Certain Internal Confidentiality Agreements or Statements--Representation (Jan 2017)

a) Definition. As used in this provision—
"Internal confidentiality agreement or statement", "subcontract", and "subcontractor", are defined in the clause at 52.203-19, Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements.

b) In accordance with section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions), Government agencies are not permitted to use funds appropriated (or otherwise made available) for contracts with an entity that requires employees or subcontractors of such entity seeking to report waste, fraud, or abuse to sign internal confidentiality agreements or statements prohibiting or otherwise restricting such employees or subcontractors from lawfully reporting such waste, fraud, or abuse to a designated investigative or law enforcement representative of a Federal department or agency authorized to receive such information.

c) The prohibition in paragraph (b) of this provision does not contravene requirements applicable to Standard Form 312, (Classified Information Nondisclosure Agreement), Form 4414 (Sensitive Compartmented Information Nondisclosure Agreement), or any other form issued by a Federal department or agency governing the nondisclosure of classified information.

d) Representation. By submission of its offer, the Offeror represents that it will not require its employees or subcontractors to sign or comply with internal confidentiality agreements or statements prohibiting or otherwise restricting such employees or subcontractors from lawfully reporting waste, fraud, or abuse related to the performance of a Government contract to a designated investigative or law enforcement representative of a Federal department or agency authorized to receive such information (e.g., agency Office of the Inspector General).

(End of provision)

52.222-35 Equal Opportunity Veterans (Oct 2015)

a) Definitions. As used in this clause—

"Active duty wartime or campaign badge veteran," "Armed Forces service medal veteran," "disabled veteran," "protected veteran," "qualified disabled veteran,' and "recently separated veteran" have the meanings given at FAR 22.1301.

b) Equal opportunity clause. The Contractor shall abide by the requirements of the equal opportunity clause at 41 CFR 60-300.5(a), as of March 24, 2014. This clause prohibits discrimination against qualified protected veterans, and requires affirmative action by the Contractor to employ and advance in employment qualified protected veterans.

c) Subcontracts. The Contractor shall insert the terms of this clause in subcontracts of $150,000 or more unless exempted by rules, regulations, or orders of the Secretary of Labor. The Contractor shall act as specified by the Director, Office of Federal Contract Compliance Programs, to enforce the terms, including action for noncompliance. Such necessary changes in language may be made as shall be appropriate of identify properly the parties and their undertakings.

(End of Clause)

52.222-36 Equal Opportunity for Workers with Disabilities (Jul 2014)

a) Equal opportunity clause. The Contractor shall abide by the requirements of the equal opportunity clause at 41 CFR 60.741.5(a), as of March 24, 2014. This clause prohibits discrimination against qualified individuals on the basis of disability, and requires affirmative action by the Contractor to employ and advance in employment qualified individuals with disabilities.

b) Subcontracts. The Contractor shall include the terms of this clause in every subcontract or purchase order in excess of $15,000 unless exempted by rules, regulations, or orders of the Secretary, so that such provisions will be binding upon each subcontractor or vendor. The Contractor shall act as specified by the Director, Office of Federal Contract Compliance Programs of the U.S. Department of Labor, to enforce the terms, including action for noncompliance. Such necessary changes in language may be made as shall be appropriate to identify properly the parties and their undertakings.

(End of Clause)

PART III – LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

J. LIST OF ATTACHMENTS

- Attachment 2: INVOICING INSTRUCTIONS FOR COST REIMBURSEMENT CONTRACTS
- Attachment 3: SAMPLE INVOICE/PAYMENT REQUEST AND CONTRACT FINANCIAL REPORT
- Attachment 4: FINANCIAL REPORT OF INDIVIDUAL PROJECT/CONTRACT
- Attachment 5: INSTRUCTION FOR COMPLETING FINANCIAL REPORT OF INDIVIDUAL PROJECT/CONTRACT
- Attachment 6: INCLUSION ENROLLMENT REPORT
- Attachment 7: RESEARCH PATIENT CARE COSTS
- Attachment 8: CONTRACTING SITE – CONTRACT NUMBER – INVENTORY SHEET
- Attachment 9: DISCLOSURE OF LOBBYING ACTIVITIES
- Attachment 10: DATA ITEM DESCRIPTION
- Attachment 11: SEVEN PRINCIPLES OF EARNED VALUE MANAGEMENT LITE

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

AMENDMENT OF SOLICITATION/MODIFICATION OF

1. CONTRACT ID CODE	PAGE OF PAGES
	1 | 1

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. *(If applicable)*
P00002	See Block 16C		

6. ISSUED BY	CODE	7. ADMINISTERED BY *(If other than Item 6)*	CODE
ASPR-BARDA 200 Independence Ave., S.W. Room 640-G Washington DC 20201	ASPR-BARDA	US DEPT OF HEALTH & HUMAN SERVICES ASST SEC OF PREPAREDNESS & RESPONSE ACQ MANAGEMENT, CONTRACTS, & GRANTS O'NEILL HOUSE OFFICE BUILDING Washington DC 20515	ASPR-BARDA02

8. NAME AND ADDRESS OF CONTRACTOR *(No., street, county, State and ZIP Code)*		9A. AMENDMENT OF SOLICITATION NO.
MODERNATX, INC 1492235 Attn: HAMILTON BENNETT MODERNATX, INC. 200 TECHNOLOGY 200 TECHNOLOGY SQ CAMBRIDGE MA 021393578	(x)	9B. DATED *(SEE ITEM 11)*
	X	10A. MODIFICATION OF CONTRACT/ORDER NO. 75A50120C00034
		10B. DATED *(SEE ITEM 13)* 04/03/2020
CODE 1492235	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 Offers ☐ is extended, ☐ is not extended.

Offers 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 electronic communication which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT 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 letter or electronic communication, provided each letter or electronic communication 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 ONLY APPLIES TO MODIFICATION OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

CHECK ONE	
	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 data, 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)* FAR 43.103(a)

E. IMPORTANT: Contractor ☐ is not ☒ is required to sign this document and return 1 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION *(Organized by UCF section headings, including solicitation/contract subject matter where feasible.)*

[***]

[***]

The purpose of this modification is to add the revised Statement of Work (SOW) dated June 3, 2020 to Option CLIN 0003. The CLIN value remains unchanged at $53,000,000. All other contract terms and conditions remain unchanged.

Except as provided herein, all terms and conditions of the document referenced in Item 9 A 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)*	
[***]		WENDELL CONYERS	
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
[***] *(Signature of person authorized to sign)*		_____ *(Signature of Contracting Officer)*	06/16/2020

Previous edition unusable

STANDARD FORM 30 (REV. 11/2016)
Prescribed by GSA FAR (48 CFR) 53.243

ACTIVE/104412070.3

Continuation Page

moderna messenger therapeutics	**Contract Number: 75A50120C00034**
Development of an mRNA Vaccine for SARS-CoV-2 **Option 1 Statement of Work** **Dated June 3, 2020**	
[***]	[***]
[***]	[***]

moderna

200 Tech Square • Cambridge, MA 02139 phone
617-714-6500 • fax 617-583-1998

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

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

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE OF PAGES
	1 | 30

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. *(If applicable)*
P00001	See Block 16C	OS259279	

6. ISSUED BY	CODE	7. ADMINISTERED BY *(If other than Item 6)*	CODE
ASPR-BARDA	ASPR-BARDA	US DEPT OF HEALTH & HUMAN SERVICES	ASPR-BARDA02
200 Independence Ave., S.W.		ASST SEC OF PREPAREDNESS & RESPONSE	
Room 640-G		ACQ MANAGEMENT, CONTRACTS, & GRANTS	
Washington DC 20201		O'NEILL HOUSE OFFICE BUILDING	
		Washington DC 20515	

8. NAME AND ADDRESS OF CONTRACTOR *(No., street, county, State and ZIP Code)*		9A. AMENDMENT OF SOLICITATION NO.
MODERNATX, INC 1492235 Attn: [***] MODERNATX, INC. 200 TECHNOLOGY 200 TECHNOLOGY SQ CAMBRIDGE MA 021393578	(x)	9B. DATED *(SEE ITEM 11)*
	x	10A. MODIFICATION OF CONTRACT/ORDER NO. 75A50120C00034
		10B. DATED *(SEE ITEM 13)* 04/03/2020
CODE 1492235	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 Offers ☐ is extended, ☐ is not extended.

Offers 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 electronic communication which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT 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 letter or electronic communication, provided each letter or electronic communication 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)*

2020.199c001.25103
Net Increase: $53,000,000.00

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

CHECK ONE	
	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 data, 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)* FAR 43.103(a)

E. IMPORTANT: Contractor ☐ is not ☒ is required to sign this document and return 1 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION *(Organized by UCF section headings, including solicitation/contract subject matter where feasible.)*

Tax ID Number: 27-0226313
DUNS Number: 069723520
The purpose of this modification is to exercise the Government s right to exercise an Option 1 CLIN 0003 - Domestic Manufacturing Scale-Out domestic manufacturing in accordance with the contract's clause FAR 52.217-9, Option to Extend the Term of the Contract.

1. The Government hereby exercises Option 1 CLIN 0003 as priced in Section B.3.2 of the Contract at a Total Price of $53,000,000.
2. Funding and Contract Total Summary: The total funded amount on the contract is hereby increased by $53,000,000 from $430,298,520 to $483,298,520 and that the total contract amount is hereby increased by $53,000,000 from $430,298,520 to $483,298,520.
3. Reference SOW Attached for Option 1 CLIN 0003

Continued ...

Except as provided herein, all terms and conditions of the document referenced in Item 9 A 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)*
Stephane Bancel, Chief Executive Officer	WENDELL CONYERS

15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
/s/ Stephane Bancel *(Signature of person authorized to sign)*		/s/ Wendell Conyers *(Signature of Contracting Officer)*	05/24/2020

CONTINUATION SHEET	REFERENCE NO. OF DOCUMENT BEING CONTINUED 75A50120C00034/P00001	PAGE 2 OF 30

NAME OF THE OFFEROR OR CONTRACTOR

MODERNATX, INC 1492235

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	Appr. Yr.: 2020 CAN: 199C001 Object Class: 25103				
	Change Item 3 to read as follows(amount shown is the obligated amount):				
3	Option 1 Kit Build-Out Obligated Amount: $53,000,000.00				53,000,000.00

moderna messenger therapeutics	**Contract Number: 75A50120C00034**
Development of an mRNA Vaccine for SARS-CoV-2 **Request to Award Option 1** Revised 8 May 2020	
Prime Contract	Moderna Therapeutics, Inc. 200 Technology Square Cambridge, MA02139-3578
Point of Contact	[***]

CONFIDENTIAL

200 Tech Square • Cambridge, MA 02139
phone 617-714-6500 • fax 617-583-1998

1-Objective:

This document outlines the current plans to enable a second node of domestic mRNA-1273 supply at Lonza's New Hampshire facility [***].

2- Approach & Estimated cost

[***]

Statement of Work Nr. 2

This Statement of Work ("SOW") is effective as of [May 8, 2020] (the "Effective Date") by and between ModernaTX, Inc., with an address at 200 Technology Square, Cambridge, MA 02139 USA ("Moderna") on the one part; and [***]

[***]

[***]

[***]

IN WITNESS WHEREOF, each Party hereto has caused this Statement of Work to be executed on its behalf by its duly authorized representative.

MODERNATX, INC	[***]
By: _____ (Signature)	By: _____ (Signature)
Print Name:	Print Name: _____
Title:	Title: _____

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

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE OF PAGES
	1 | 1

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. *(If applicable)*
P00002	See Block 16C		

6. ISSUED BY	CODE	7. ADMINISTERED BY *(If other than Item 6)*	CODE
ASPR-BARDA	ASPR-BARDA	US DEPT OF HEALTH & HUMAN SERVICES	ASPR-BARDA02
200 Independence Ave., S.W.		ASST SEC OF PREPAREDNESS & RESPONSE	
Room 640-G		ACQ MANAGEMENT, CONTRACTS, & GRANTS	
Washington DC 20201		O'NEILL HOUSE OFFICE BUILDING	
		Washington DC 20515	

8. NAME AND ADDRESS OF CONTRACTOR *(No., street, county, State and ZIP Code)*		9A. AMENDMENT OF SOLICITATION NO.
MODERNATX, INC 1492235	(x)	
Attn: [***]		9B. DATED *(SEE ITEM 11)*
MODERNATX, INC. 200 TECHNOLOGY		
200 TECHNOLOGY SQ	X	10A. MODIFICATION OF CONTRACT/ORDER NO. 75A50120C00034
CAMBRIDGE MA 021393578		10B. DATED *(SEE ITEM 13)* 04/03/2020

CODE 1492235	FACILITY CODE

15. 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 Offers ☐ is extended, ☐ is not extended.

Offers 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 electronic communication which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT 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 letter or electronic communication, provided each letter or electronic communication makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

16. ACCOUNTING AND APPROPRIATION DATA *(If required)*
See Schedule

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

CHECK ONE	
	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 data, 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)* FAR 43.103(a)

E. IMPORTANT: Contractor ☐ is not ☒ is required to sign this document and return 1 copies to the issuing office.

18. DESCRIPTION OF AMENDMENT/MODIFICATION *(Organized by UCF section headings, including solicitation/contract subject matter where feasible.)*

Tax ID Number: 27-0226313
DUNS Number: 069723520
The purpose of this modification is to add the revised Statement of Work (SOW) dated June 3, 2020 to the Option CLIN 0003. The CLIN value remains unchanged at $53,000,000. All other contract terms and conditions remain unchanged.

Except as provided herein, all terms and conditions of the document referenced in Item 9 A 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)*	
Stephane Bancel, Chief Executive Officer		WENDELL CONYERS	
15B. CONTRACTOR/OFFEROR	**15C. DATE SIGNED**	**16B. UNITED STATES OF AMERICA**	**16C. DATE SIGNED**
/s/ Stephane Bancel *(Signature of person authorized to sign)*	6/4/2020	/s/ Wendell Conyers *(Signature of Contracting Officer)*	6/16/2020

Continuation Page

moderna messenger therapeutics	**Contract Number: 75A50120C00034**
Development of an mRNA Vaccine for SARS-CoV-2 **Option 1 Statement of Work** **Dated June 3, 2020**	
Prime Contract	Moderna Therapeutics, Inc. 200 Technology Square Cambridge, MA02139-3578
Point of Contact	[***]

CONFIDENTIAL

moderna

200 Tech Square • Cambridge, MA 02139
phone 617-714-6500 • fax 617-583-1998

1-Objective:

This document outlines the current plans to enable a second node of domestic mRNA-1273 supply at Lonza's New Hampshire facility [***]

2-Approach & Estimated cost:

[***]

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

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE OF PAGES
	1 39

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. (If applicable)
P00003	See Block 16C	OS262588	

6. ISSUED BY	CODE	7. ADMINISTERED BY (If other than Item 6)	CODE
ASPR-BARDA	ASPR-BARDA	US DEPT OF HEALTH & HUMAN SERVICES	ASPR-BARDA02
200 Independence Ave., S.W.		ASST SEC OF PREPAREDNESS & RESPONSE	
Room 640-G		ACQ MANAGEMENT, CONTRACTS, & GRANTS	
Washington DC 20201		O'NEILL HOUSE OFFICE BUILDING	
		Washington DC 20515	

8. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and ZIP Code)		9A. AMENDMENT OF SOLICITATION NO.
MODERNATX, INC 1492235	(x)	
Attn: [***]		9B. DATED (SEE ITEM 11)
MODERNATX, INC. 200 TECHNOLOGY		
200 TECHNOLOGY SQ		10A. MODIFICATION OF CONTRACT/ORDER NO.
CAMBRIDGE MA 021393578	x	75A50120C00034
		10B. DATED (SEE ITEM 13)
CODE 1492235	FACILITY CODE	04/03/2020

19. 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 Offers ☐ is extended, ☐ is not extended.

Offers 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 electronic communication which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT 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 letter or electronic communication, provided each letter or electronic communication makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

20. ACCOUNTING AND APPROPRIATION DATA *(If required)*
See Schedule
Net Increase: $471,596,459.00

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

CHECK ONE	
	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 data, 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)* FAR 43.103(a)

E. IMPORTANT: Contractor ☐ is not ☒ is required to sign this document and return 1 copies to the issuing office.

22. DESCRIPTION OF AMENDMENT/MODIFICATION *(Organized by UCF section headings, including solicitation/contract subject matter where feasible.)*

Tax ID Number:27-0226313
DUNS Number: 069723520
The purpose of this modification is to support the additional scope of the Clinical Development Plan including direct increases to the clinical subcontractors on the P201 (Work Breakdown Structure 1.4.2.1) and P301 (Work Breakdown Structure 1.4.3.1) clinical studies, and forecasted overruns across the remaining WBS elements. This modification with Moderna to develop a mRNA vaccine for SARS-CoV-2 is part of the USG effort to accelerate the development, manufacturing, and distribution of COVID-19 vaccines, therapeutics, and diagnostics (medical countermeasures) in the midst of a global novel coronavirus pandemic.

As a result of the additional scope, the following was updated in this modification.

Continued ...

Except as provided herein, all terms and conditions of the document referenced in Item 9 A 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)*	
Stephane Bancel, Chief Executive Officer		WENDELL CONYERS	
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
/s/ Stephane Bancel *(Signature of person authorized to sign)*	7-25-20	_____ *(Signature of Contracting Officer)*	

CONTINUATION SHEET	REFERENCE NO. OF DOCUMENT BEING CONTINUED 75A50120C00034/P00003	PAGE 2	OF 39

NAME OF OFFEROR OR CONTRACTOR
MODERNATX, INC 1492235

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	- Increase in total contract value from $483,298,520 to $954,894,979; - Section B.4.14 Enrollment Chart - Section C.2 Statement of Work - Section C.2.1 Development Approach - Section F.1.6. Organizational Chart - Section F.1.7. Contractor Provided Facilities, Infrastructure and Other Resources - Section F.2 Deliverables - Section F.3 Contract WBS Milestones/Deliverables and Technical Deliverables - Section H.3 Key Personnel - Section H.9 Security - Section H.20 Organizational Conflicts of Interest - Section H.21 Disclosure of Information - Section H.22 Publication and Publicity - Section H.23 Vetting Period of Performance: [***] Change Item 2 to read as follows (amount shown is the obligated amount):				
2	Base CLIN 0002 - Development of mRNA vaccine to BLA [***] [***] [***] Funded: $471,596,459.00				471,596,459.00

Contract No. 75A50120C00034 Mod P00003
Moderna - Development of an mRNA Vaccine for SARS-CoV-2

CONTINUATION PAGE

1. Modification Purpose

The purpose of this modification is to support the additional scope of the Clinical Development Plan including direct increases to the clinical subcontractors on the P201 (Work Breakdown Structure 1.4.2.1) and P301 (Work Breakdown Structure 1.4.3.1) clinical studies, and forecasted overruns across the remaining WBS elements. This modification with Moderna to develop a mRNA vaccine for SARS-CoV-2 is part of the USG effort to accelerate the development, manufacturing, and distribution of COVID-19 vaccines, therapeutics, and diagnostics (medical countermeasures) in the midst of a global novel coronavirus pandemic.

As a result of the additional scope, the following was updated in this modification.

- Increase in total contract value from $483,298,520 to $954,894,979;
- Section B.4.14 Enrollment Chart
- Section C.2 Statement of Work
- Section C.2.1 Development Approach
- Section F.1.6. Organizational Chart
- Section F.1.7. Contractor Provided Facilities, Infrastructure and Other Resources
- Section F.2 Deliverables
- Section F.3 Contract WBS Milestones/Deliverables and Technical Deliverables
- Section H.3 Key Personnel
- Section H.9 Security
- Section H.20 Organizational Conflicts of Interest
- Section H.21 Disclosure of Information
- Section H.22 Publication and Publicity
- Section H.23 Vetting

2. Modification to Contract

This modification adds $471,596,459 to CLIN 0002 and increases the total contract value from $483,298,520 to $954,894,979. [***]

CLIN 0003 POP extends to [***] at no additional cost.

Period	CLIN	Awarded 4/16/2020	Additional Scope	Total Contract
Pre Award	CLIN 0001	[***]	[***]	[***]
Base	CLIN 0002	[***]	[***]	[***]
Option 1	CLIN 0003	[***]	[***]	[***]
Total		$483,298,520	$471,596,459	$954,894,979

The period of performance changes
[***]

Contract No. 75A50120C00034 Mod
P00003
Moderna - Development of an mRNA Vaccine for SARS-CoV-2

B.4.14 Enrollment Chart

[***]

	Unit Price	Unit Qty	Total	
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]
		[***]	**[***]**	**[***]**

[***]

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

[***]

C.2 Statement of Work (Revised 7-14-2020) Updates to WBS 1.4.2.1 and 1.4.3.1 Only

Independently, and not as an agent of the United States Government, the contractor shall furnish all necessary services, qualified professional, technical, and administrative personnel, material, equipment and facilities, not otherwise provided by the Government under the terms of this contract, as needed to perform the tasks set forth below.

mRNA-1273 Vaccine Development (WBS 1.0)

The Contractor, ModernaTX, Inc. ("Moderna") shall execute the preclinical, clinical, and chemistry, manufacturing and controls (CMC) activities required to license a vaccine against the SARS-CoV-2 virus (hereafter referred to as "mRNA-1273"). Building upon early clinical development already underway, this proposal will support the late stage development, including the demonstration of clinical efficacy and generation of a dataset supportive of licensure. Moderna will additionally evaluate the platform manufacturing capabilities relative to the needs for supply in response to a pandemic.

Program Management (WBS 1.1)

mRNA-1273 Program Management (WBS 1.1.1)

Moderna's mRNA-1273 program team is composed of a multidisciplinary, highly matrixed, group of functional leads with experience in, and responsibility for, integrating plans and operationalizing strategies across Research, Toxicology, CMC, Regulatory Affairs, Clinical Development and Quality. Collectively, the team has advanced ten programs to first-in-human studies within fiveyears. The group will be led by a program lead (PL) who will oversee and coordinate the activities necessary to meet program objectives. The PL will be the point of accountability for the development of mRNA-1273. [***] A program management office (PMO) will be responsible for managing the cost and schedule constraints of the contract via an integrated master schedule and corresponding budget, identifying and managing program risk, and ensuring contract compliance. With the input from the mRNA-1273 project team, the PMO will be responsible for coordinating the drafting of and management to an integrated development plan. Upon execution of the contract, weekly meetings with BARDA will be held to monitor program performance and monthly and annual reports will be will delivered to BARDA for the record.

Nonclinical Toxicology (WBS 1.2)

Development and Reproductive Toxicology of mRNA-1273 (WBS 1.2.2.1)

To assess the risk of administering the vaccine to pregnant women, a complete GLP rat developmental and reproductive toxicology (DART) study is planned. Female Sprague Dawley rats will be dosed at the highest anticipated clinical dose level and include a control arm of phosphate-buffered saline (PBS). As is typical for DART evaluations for vaccines, the animals will be immunized three times prior to mating and two times during gestation. Each group will have two cohorts (one group will undergo Cesarean section with examination of the uteri and embryos; the other group will have natural delivery and will be terminated at weaning).

Nonclinical (WBS 1.3)

For the purposes of this proposal it is assumed that the VRC continues to support nonclinical activities to develop murine and non-human primate efficacy studies, and animal models to assess the potential of vaccine-enhanced disease. The scope of work below will execute additional robustness experiments in these developed models.

Assess Disease Enhancement (WBS 1.3.3.1)
[***]

We plan to perform studies in mouse and NHPs to assess the theoretical risk of vaccine induced disease enhancement triggered by CoV infection following vaccination with imRNA-1273.
[***]

Establish a Surrogate of Protection (WBS 1.3.3.2)
The primary endpoint for accelerated approval of a SARS-CoV-2 vaccine would be a neutralization assay. This endpoint must be supported with a body of pre-clinical work that demonstrates a correlation between neutralizing titers and efficacy and that quantifies a protective serologic threshold titer using the same neutralization assay. Murine and NHP efficacy models are being developed in parallel to the Phase 1

clinical study. Building on data from these preliminary models and studies, Moderna will conduct NHP efficacy and murine passive transfer studies to confirm and refine the surrogate of protection.
Clinical (WBS 1.4)
[***]

***Phase 2 Safety and Immunogenicity Study* (WBS 1.4.2.1) - Updated**
[***]

Phase 3 Pivotal Study:(WBS 1.4.3.1) - Updated

Phase 3 Pivotal Study (WBS 1.4.3.1). The Phase 3 mRNA-1273-P301 study will confirm the trends observed during the Phase 1 and 2 trials, evaluating safety and efficacy in a larger number of subjects aged 18 and above. Approximately 30,000 subjects will be enrolled according to 1:1 randomization (active: placebo). Primary objectives will be 1) to demonstrate the efficacy of mRNA-1273 to prevent COVID-19

and 2) to evaluate the safety and reactogenicity of 2 injections of the mRNA-1273 vaccine given 28 days apart. [***]

Lot to Lot Consistency (WBS 1.4.3.2)
[***]

Pediatrics (WBS 1.4.3.3)
[***]

Regulatory (WBS 1.5)

IND Preparation and Filing (WBS 1.5.1.1)

Moderna's Regulatory Affairs group, in close collaboration with BARDA, will work to draft a comprehensive regulatory master plan to guide the preclinical, CMC and clinical development of mRNA-1273 within the first 90 days of the contract. An original investigational new drug application (IND) will

be filed with the United States Food and Drug Administration (FDA) to support the clinical development of the Moderna product from Phase 2 onwards.

IND Maintenance (WBS 1.5.1.2)
The Moderna-owned IND will be maintained to support the desired clinical development plan. As needed, meetings will be conducted to receive feedback and gain concurrence on the specifics of the development activities with the FDA.

BLA Submission (WBS 1.5.2.1)
Moderna will submit a Biologics License Application (BLA) and seek approval for the mRNA-1273 vaccine.
CMC (WBS 1.6)
CTM Manufacture for Phase 2 (WBS 1.6.3.2)
[***]

Process Development for Late Stage Clinical Supply (WBS 1.6.3.3)
mRNA Process Development
Technical Development will confirm and optimize the process parameters for mRNA manufacture. [***]

BLA Readiness (WBS 1.6.3.8)
In support of the Biologics License Application (BLA) due to the nature of the proposed timeline, it is likely that Moderna will need to complete some of process validation activities, primarily process characterization, after the completion of process performance qualification and before BLA filing. Moderna intends to rapidly develop a robust process for clinical manufacturing and PPQ, and then fully describe the acceptable design space for the process prior to BLA filing. Other activities to support this BLA filing, such as completing raw material qualification activities; if not included in the BLA submission, will require a supplement to the initial BLA. In the initial BLA filing Moderna will describe its control strategy to cover the gap between initial BLA filing and the BLA supplement.

Process Development for Full Commercial Scale (WBS 1.6.4.1)
The following section outlines the process development activities [***]. The goal of this work is to demonstrate the capability to produce mRNA- 1273 at a scale that can support clinical demand.
[***]

[***]

Stability Studies (WBS 1.6.5.4)
Throughout the program, many studies will be undertaken [***]. This includes studies using development bench scale material, engineering lot material, and GMP material. This body of data will be used to apply interim and long-term shelf life to the drug product and process intermediates.

C.2.1. Development Approach
[***]

F.3 Contract WBS Milestones/Deliverables and Technical Deliverables

Work Breakdown Structure (WBS), Go/No Go Program Stage Gates Gantt Chart, Integrated Master Schedule (IMS)

Work Breakdown Structure and Option Periods

[***]

F.3. Deliverables

The primary deliverable of this proposal is a licensed mRNA-1273 vaccine. In addition, the team, in partnership with BARDA, will also design a plan to enhance Moderna's ability to rapidly respond to a Coronavirus pandemic by leveraging our mRNA platform. Interim deliverables are presented below.

WBS	Title	Deliverable	Timing
1	mRNA-1273 Vaccine Development		
1.1	Program Management		
1.1.1	Program and Alliance Management	-Management Plans; Routine Reporting Deliverables	[***]
1.2	Nonclinical Toxicology		
1.2.2	Safety		
1.2.2.1	Development and Reproductive Toxicology	- Final Study Report	[***]
1.3	Nonclinical		
1.3.1	Model Development (reserved)		
1.3.1.2	NHP Efficacy Study	- Final Study Report	[***]
1.3.1.3	Mouse Efficacy Study	- Final Study Report	[***]
1.4	Clinical		
1.4.2	Phase 2		
1.4.2.1	Phase 2 Safety and Immunogenicity Study	- Clinical Study Protocol	[***]
		- Final Clinical Study Report	[***]
1.4.3	Phase 3		
1.4.3.1	Phase 3 Efficacy or Safety and Immunogenicity	- Clinical Study Protocol	[***]
		- Final Clinical Study Report	[***]
1.4.3.2	Phase 3 Lot-to-Lot	- Clinical Study Protocol	[***]
		- Final Clinical Study Report	[***]
1.4.3.3	Phase 3 Adolescents	- Clinical Study Protocol	[***]
		- Final Clinical Study Report	[***]
	Regulatory		
1.5.1	IND		
1.5.1.1	IND Filing	- NA	
1.5.1.2	IND Maintenance	- Record of FDA Communications	[***]
1.5.2	BLA		[***]
1.5.2.1	BLA Submission	- NA	
1.6	CMC		
1.6.3	Pilot Scale Manufacturing		
1.6.3.2	CTM Manufacture for P201	- CoA for Clinical Lots	[***]
1.6.3.4	CTM Manufacture for P301	- CoA for Clinical Lots	[***]
1.6.3.6	CTM Manufacture for P302/P303	- CoA for Clinical Lots	[***]

H.3 Key Personnel

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

F.1.6. Organizational Chart

The organizational chart depicts the project team reporting structure of the key personnel for the scope of work for this proposal. [***]

[***]

ARTICLE F.2. DELIVERABLES SCHEDULE

ARTICLE F.2. DELIVERABLES

Successful performance of the final contract shall be deemed to occur upon performance of the work set forth in the Statement of Work attached to this contract as Attachment 1 (SECTION J-List of Attachments), and upon delivery and acceptance, as required by the Statement of Work, by the Contracting Officer, or the duly authorized representative pursuant to SECTION E-Inspection and Acceptance, of the following items listed below under heading 1 "Summary of Contract Deliverables" in accordance with the stated delivery schedule.

The items specified below under heading 1 "Summary of Contract Deliverables", as described in the Statement of Work which is Attachment 1 to this contract will be required to be delivered by the date(s) specified below and in accordance with any specifications stated in SECTION D- PACKAGING, MARKING AND SHIPPING, of this contract. All reports identified below relate solely to the development activity funded under this contract:

1. **Summary of Contract Deliverables**

Unless otherwise stated, each deliverable in the table below shall be provided as one (1) electronic copy to the contracting officer representative (COR), contract specialist (CS), and contracting officer (CO) as set forth in SECTION D.

In addition to or in replacement of electronic copies, the CO may direct the Contractor to submit the below deliverables via BARDA Digital Resources Portal in machine-readable format.

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
01	**Meetings**		
01.6	Daily check in with project staff for **COVID-19 Contract**	Upon request of the Government, the Contractor shall participate in a daily check-in update with the project staff (via teleconference or email). The updates will address key cost, schedule and technical updates. Daily updates may be shared with senior Government leaders during the COVID- 19 response and should be provided on a non-confidential basis, unless the update includes confidential information in which case	• No agenda will be required for the meeting • No meeting minutes are required • Contractor will provide bulleted email updates following any call or in lieu of a call by 2PM for that day

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		Contractor shall provide the update in both confidential and non-confidential formats. Daily check-ins may occur on weekdays, excluding federal holidays. Upon request of the Government, check-ins may also occur on weekends and on federal holidays, provided at least 24 hours' notice.	
02	**Technical Reporting**		
02.8	Product Development Source Material and Manufacturing Reports and Projections	The Contractor shall submit a detailed spreadsheet regarding critical project materials that are sourced from a location other than the United States, sources, and manufacturing sites, including but not limited to: physical locations of sources of raw and processed material by type of material; location and nature of work performed at manufacturing sites; and location and nature of non- clinical and clinical study sites. **The Contractor will provide manufacturing reports and manufacturing dose tracking projections/actuals utilizing the "COVID-19 Dose Tracking Templates", on any contract/agreement that is manufacturing product for the USG**	• Contractor will submit Product Development Source Material Report ○ Within month of contract award ○ Within 30 days of substantive changes are made to sources and/or materials ○ Or on the 6th month contract anniversary. • Contractor will update the Dose Tracking Template weekly, during manufacturing campaigns and COVID response, with the first deliverable submission within 15 days of award/modification. Updates to be provided weekly. • The Government will provide written comments to the Product Development Source Material and Manufacturing Report within 15 business days after the submission • If corrective action is recommended, Contractor must address all concerns raised by BARDA in writing
02.9	Contractor Locations	The contractor shall submit detailed data regarding locations where work will be performed	Contractor will submit Work Locations Report:

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		under this contract, including addresses, points of contact, and work performed per location, to include sub-contractors.	• Within 5 business days of contract award • Within 30 business days after a substantive location or capabilities change • Within 2 business days of a substantive change if the work performed supports medical countermeasure development that addresses a threat that has been declared a Public Health Emergency by the HHS Secretary or a Public Health Emergency of International Concern (PHEIC) by the WHO
09	**Advanced R&D Products**		

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
09.5	Contractor Publication Timeline and USG Right to Publish Data	The Contractor and Government are committed to transparent and timely publication of clinical trial data to ensure rapid distribution of information during the COVID-19 Pandemic. Within 30 days of the primary analysis, results from clinical studies funded in whole or in part under this contract and consistent with Good Publications Practices. Sponsor must publish the primary endpoint analysis. Within 90 days of the of study end date [last subject last visit] for studies funded in part or whole under this contract and consistent with Good Publication Practices sponsor shall publish clinical trial data. If the contractor does not elect to publish data, Contractor shall provide CO and COR with clinical trial data to support the government publication of data as deemed appropriate by the government, without the contractor involvement.	• Contractor shall notify CO and within 30 of primary analysis results and study end date [last subject last visit] if they plan not to publish data. • Within 10 calendar days of a request for clinical data from the CO, the Contractor shall provide CO with requested data, information and materials in the form(s) requested by the government, to support the government publication of the clinical trial data funded in part or whole under this contract
09.6	Additional Clinical Trial Deliverables	Contractor shall provide read-only access to clinical trials management system [***] Contractor shall provide for review for all study operational	Contractor shall provide upon request of the CO or COR.

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		plans prior to finalization including but not limited: 1. Global communication plan 2. Project management plan 3. Study subject recruitment/retention plan 4. Clinical monitoring plan 5. Medical monitoring plan 6. Safety management plan 7. Laboratory manual 8. Study procedures manual 9. Sample management plan 10. Clinical supply management plan 11. Quality management plan 12. Data management plan 13. Statistical analysis plan	

C.4 Target Product Profile

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

H.19 Security

BARDA Security Requirements:
All COVID-19 contracts are required to address security requirements. In the event that Moderna does not have another contract in place with the USG within 45 days of execution of this contract modification that incorporates the security requirement, Moderna will submit a cost estimate for implementing security requirements for this contract. Moderna will be entitled to an equitable upward adjustment in the value of this contract to cover all additional costs associated with additional security requirements imposed by the Government.

H.20 Organizational Conflicts of Interest

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

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

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

Whenever performance of this contract provides access to another Contractor's proprietary information, the Contractor shall:

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

H.21 Disclosure of Information

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

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

No information related to data obtained under this contract shall be released or publicized without the prior written consent of the COR, whose approval shall not be unreasonably withheld, conditioned, or delayed, provided that no such consent is required to comply with any law, rule, regulation, court ruling or similar order; for submission to any government entity' for submission to any securities exchange on which the Contractor's (or its parent corporation's) securities may be listed for trading; or to third parties relating to securing, seeking, establishing or maintaining regulatory or other legal approvals or compliance, financing and capital raising activities, or mergers, acquisitions, or other business transactions.

H. 22 PUBLICATION AND PUBLICITY

The contractor shall not release any reports, manuscripts, press releases, or abstracts about the work being performed under this contract without written notice in advance to the Government, for additional information see HHSAR 352.227-70. Publications and Publicity (Dec 2015).
(a) Unless otherwise specified in this contract, the contractor may publish the results of its work under this contract. The contractor shall promptly send a copy of each submission to the COR for security review prior to submission. The contractor shall also inform the COR when the abstract article or other publication is published, and furnish a copy of it as finally published.

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

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)*
P00004	See Block 16C		

6. ISSUED BY CODE ASPR-BARDA

ASPR-BARDA
200 Independence Ave., S.W.
Room 640-G
Washington DC 20201

7. ADMINISTERED BY *(If other than Item 6)* CODE ASPR-BARDA02

US DEPT OF HEALTH & HUMAN SERVICES
ASST SEC OF PREPAREDNESS & RESPONSE
ACQ MANAGEMENT, CONTRACTS, & GRANTS
O'NEILL HOUSE OFFICE BUILDING
Washington DC 20515

8. NAME AND ADDRESS OF CONTRACTOR *(No., street, county, State and ZIP Code)*

MODERNATX, INC 1492235
Attn: [***]
MODERNATX, INC. 200 TECHNOLOGY
200 TECHNOLOGY SQ
CAMBRIDGE MA 021393578

CODE 1492235 FACILITY CODE

(x) 9A. AMENDMENT OF SOLICITATION NO.

9B. DATED *(SEE ITEM 11)*

X 10A. MODIFICATION OF CONTRACT/ORDER NO. 75A50120C00034

10B. DATED *(SEE ITEM 13)* 04/03/2020

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 Offers ☐ is extended, ☐ is not extended.

Offers 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 electronic communication which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT 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 letter or electronic communication, provided each letter or electronic communication 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 ONLY APPLIES TO MODIFICATION OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

CHECK ONE	
	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 data, 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)* FAR 43.103(a)

E. IMPORTANT: Contractor ☐ is not ☒ is required to sign this document and return 1 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION *(Organized by UCF section headings, including solicitation/contract subject matter where feasible.)*

Tax ID Number: 27-0226313
DUNS Number: 069723520
The purpose of this modification is to add the Defense Priorities and Allocations System (DPAS) priority rating language to the contract. The modification changes the contract from unrated to a DO-H5 rating at no additional cost.
Section B.4.14 DPAS PRIORITY RATING has been added to the contract. Reference the Continuation Page for detail.

All other contract terms and conditions remain unchanged.

Continued...

Except as provided herein, all terms and conditions of the document referenced in Item 9 A 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)*	
Stephane Bancel, Chief Executive Officer		WENDELL CONYERS	
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
/s/ Stephane Bancel *(Signature of person authorized to sign)*	8/31/2020	/s/ Wendell Conyers *(Signature of Contracting Officer)*	8/31/2020

CONTINUATION SHEET	REFERENCE NO. OF DOCUMENTS BEING CONTINUED 75A50120C00034/P00004	PAG 2 | 4

NAME OF OFFEROR OR CONTRACTOR
MODERNATX, INC 1492235

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	Period of Performance: [***]				

CONTINUATION PAGE

B.4 Advanced Understandings

B.4.14 DPAS PRIORITY RATING

This is a **DO rated order** for the purpose of emergency preparedness and the Contractor shall follow all the provisions of the Defense Priorities and Allocations System regulation (15 CFR Part700). If the contractor needs to utilize industrial resources to fulfill this rated order for capacity and industrial expansion, it is authorized pursuant to 15 CFR §700.16(b) to place the same priority rating and program identification symbol on its orders for industrial resources with its suppliers.

DPAS PRIORITY RATING LANGUAGE:

The purpose of this no cost bilateral modification is to provide notice that this is a priority **DO-H5 rated** Contract #75A50120C00034. The Contractor and its subcontractors at all tiers are required to follow all of the provisions of the *Defense Priorities and Allocations System regulation (15 C.F.R. part 700)* as this contract is certified for national defense and emergency preparedness use. The authority for this rating is attached (Attachment A). The priority rating issued pursuant to the authorization is subject to the restrictions in the authorization.

The Parties agree that this change from an unrated contract to a DO-H5 priority rated is a no-cost change. Upon execution of this modification, the Contractor and its subcontractors must give the appropriate preferential treatment to the contract as of the date of the modification. The Contractor shall accept, perform, and prioritize this contract.

The Parties agree that this modification to rate this contract does not significantly alter the production or delivery schedule already in existence under this contract.

This contract shall take precedence over any and all other contracts and orders that do not have a priority rating and shall take precedence over orders or contracts that have the same level of priority rating but were received later in time.

This priority rating allows the Contractor to priority rate orders to its subcontractors and suppliers for purpose of fulfilling the priority-rated order expediently.

This priority rating automatically expires at the end of the contract's period of performance. The parties agree that the U.S. Government (USG) may withdraw or extend this authorization at any time prior to the expiration of the contract's period of performance at no cost to the USG.

If the Contractor and/or its subcontractors are unable to comply fully with the terms of this rated order Clause, the Contractor must immediately notify the Assistant Secretary for Preparedness and Response (ASPR) in writing and explain the extent to which compliance is possible and provide reasons why full compliance is not possible.

The contractor understands that use of this DO-rating can only be used for the procurement of raw materials, consumables, equipment, etc. necessary for the work covered under the scope of this contract.

The Contractor agrees that the Government's right to exercise priorities and allocations authority with respect to this contract to include the use of directives constitutes a no-cost change to this contract. The written signature on a manually placed order, or the digital signature or name on an electronically placed order, of an individual authorized to sign rated orders for the person placing the order is

provided. The signature, manual or digital, certifies that the rated contract is authorized under this regulation and that the requirements of this regulation are being followed. This language shall be added to the contract or task order by modification, if previously awarded.

This is a rated order certified for national defense use and you are required to follow all provisions of the Defense Priorities and Allocations System regulations (15 CFR part 700). This rated order is placed for the purpose of emergency preparedness.

The Parties agree that this modification includes the following documents:

Attachment Number	Title	Date
A	Authorization to issue Defense Priorities and Allocations System Rating for Operation Warp Speed Contract – ModernaTx. Inc.	August 30, 2020

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

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE OF PAGES
	1 11

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. (If applicable)
P00005	See Block 16C		

6. ISSUED BY	CODE	7. ADMINISTERED BY (If other than Item 6)	CODE
ASPR-BARDA	ASPR-BARDA	US DEPT OF HEALTH & HUMAN SERVICES	ASPR-BARDA02
200 Independence Ave., S.W.		ASST SEC OF PREPAREDNESS & RESPONSE	
Room 640-G		ACQ MANAGEMENT, CONTRACTS, & GRANTS	
Washington DC 20201		O'NEILL HOUSE OFFICE BUILDING	
		Washington DC 20515	

8. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and ZIP Code)		9A. AMENDMENT OF SOLICITATION NO.
MODERNATX, INC 1492235 Attn: [***] MODERNATX, INC. 200 TECHNOLOGY 200 TECHNOLOGY SQ CAMBRIDGE MA 021393578	(x)	9B. DATED (SEE ITEM 11)
	x	10A. MODIFICATION OF CONTRACT/ORDER NO. 75A50120C00034
		10B. DATED (SEE ITEM 13) 04/03/2020
CODE 1492235	FACILITY CODE	

23. 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 Offers ☐ is extended, ☐ is not extended.

Offers 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 electronic communication which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT 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 letter or electronic communication, provided each letter or electronic communication makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

24. ACCOUNTING AND APPROPRIATION DATA *(If required)*

See Schedule

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

CHECK ONE	
	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 data, 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)* FAR 43.103(a)

E. IMPORTANT: Contractor ☐ is not ☒ is required to sign this document and return 1 copies to the issuing office.

26. DESCRIPTION OF AMENDMENT/MODIFICATION *(Organized by UCF section headings, including solicitation/contract subject matter where feasible.)*

Tax ID Number: 27-0226313
DUNS Number: 069723520
The purpose of this modification is to revise the Statement of Work (SOW) to reflect recent feedback from the FDA and OWS on the clinical development plan, and to reallocate the resulting funding to the ongoing mRNA-1273-P301 clinical study.

As a result of the additional scope, the following was updated in this modification.
- Section B.4.14 Enrollment Chart
- Section C.2 Statement of Work
- This modification reallocates up to $48,137,292 within CLIN 0002

Continued ...

Except as provided herein, all terms and conditions of the document referenced in Item 9 A 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)*	
Stephane Bancel, Chief Executive Officer		WENDELL CONYERS	
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
/s/ Stephane Bancel *(Signature of person authorized to sign)*	9/15/2020	/s/ Wendell Conyers *(Signature of Contracting Officer)*	Sept. 5, 2020

CONTINUATION SHEET	REFERENCE NO. OF DOCUMENT BEING CONTINUED 75A50120C00034/P00005	PAGE 2	OF 11

NAME OF OFFEROR OR CONTRACTOR
MODERNATX, INC 1492235

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	All other contract terms and conditions remain unchanged.				
	Period of Performance: [***]				

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CONTINUATION PAGE

B.4.14 Enrollment Chart

[***]

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C. Statement of Work – Dated 9-14-2020

Independently, and not as an agent of the United States Government, the contractor shall furnish all necessary services, qualified professional, technical, and administrative personnel, material, equipment and facilities, not otherwise provided by the Government under the terms of this contract, as needed to perform the tasks set forth below.

mRNA-1273 Vaccine Development (WBS 1.0)

The Contractor, Moderna, Inc. ("Moderna") shall execute the preclinical, clinical, and chemistry, manufacturing and controls (CMC) activities required to license a vaccine against the SARS-CoV-2 virus (hereafter referred to as "mRNA-1273"). Building upon early clinical development already underway, this proposal will support the late stage development, including the demonstration of clinical efficacy and generation of a dataset supportive of licensure. Moderna will additionally evaluate the platform manufacturing capabilities relative to the needs for supply in response to a pandemic.

Program Management (WBS 1.1)

mRNA-1273 Program Management (WBS 1.1.1)

Moderna's mRNA-1273 program team is composed of a multidisciplinary, highly matrixed, group of functional leads with experience in, and responsibility for, integrating plans and operationalizing strategies across Research, Toxicology, CMC, Regulatory Affairs, Clinical Development and Quality. Collectively, the team has advanced ten programs to first-in-human studies within five years. The group will be led by a program lead (PL) who will oversee and coordinate the activities necessary to meet program objectives. The PL will be the point of accountability for the development of mRNA-1273. [***]. A program management office (PMO) will be responsible for managing the cost and schedule constraints of the contract via an integrated master schedule and corresponding budget, identifying and managing program risk, and ensuring contract compliance. With the input from the mRNA-1273 project team, the PMO will be responsible for coordinating the drafting of and management to an integrated development plan. Upon execution of the contract, weekly meetings with BARDA will be held to monitor program performance and monthly and annual reports will be will delivered to BARDA for the record.

Nonclinical Toxicology (WBS 1.2)

Development and Reproductive Toxicology of mRNA-1273 (WBS 1.2.2.1)

To assess the risk of administering the vaccine to pregnant women, a complete GLP rat developmental and reproductive toxicology (DART) study is planned. Female Sprague Dawley rats will be dosed at the highest anticipated clinical dose level and include a control arm of phosphate-buffered saline (PBS). As is typical for DART evaluations for vaccines, the animals will be immunized three times prior to mating and two times during gestation. Each group will have two cohorts (one group will undergo Cesarean section with examination of the uteri and embryos; the other group will have natural delivery and will be terminated at weaning).

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Nonclinical (WBS 1.3)

For the purposes of this proposal it is assumed that the VRC continues to support nonclinical activities to develop murine and non-human primate efficacy studies, and animal models to assess the potential of vaccine-enhanced disease. The scope of work below will execute additional robustness experiments in these developed models.

Assess Disease Enhancement (WBS 1.3.3.1)

[***]

We plan to perform studies in mouse and NHPs to assess the theoretical risk of vaccine induced disease enhancement triggered by CoV infection following vaccination with imRNA-1273. [***]

[***]

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Establish a Surrogate of Protection (WBS 1.3.3.2)

The primary endpoint for accelerated approval of a SARS-CoV-2 vaccine would be a neutralization assay. This endpoint must be supported with a body of pre-clinical work that demonstrates a correlation between neutralizing titers and efficacy and that quantifies a protective serologic threshold titer using the same neutralization assay. Murine and NHP efficacy models are being developed in parallel to the Phase 1 clinical study. Building on data from these preliminary models and studies, Moderna will conduct NHP efficacy and murine passive transfer studies to confirm and refine the surrogate of protection.

Clinical (WBS 1.4)

[***]

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[***]

Phase 3 Pivotal Study (WBS 1.4.3.1)

Phase 3 Pivotal Study (WBS 1.4.3.1). The Phase 3 mRNA-1273-P301 study will confirm the trends observed during the Phase 1 and 2 trials, evaluating safety and efficacy in a larger number of subjects aged 18 and above. Approximately 30,000 subjects will be enrolled according to 1:1 randomization (active: placebo). Primary objectives will be 1) to demonstrate the efficacy of mRNA-1273 to prevent COVID-19 and 2) to evaluate the safety and reactogenicity of 2 injections of the mRNA-1273 vaccine given 28 days apart. [***]

[***]

Lot to Lot Consistency (WBS 1.4.3.2)
Based on FDA feedback received on 27 Aug this study is no longer required for licensure.

Pediatrics (WBS 1.4.3.3)
[***]

Regulatory (WBS 1.5)

IND Preparation and Filing (WBS 1.5.1.1)
Moderna's Regulatory Affairs group, in close collaboration with BARDA, will work to draft a comprehensive regulatory master plan to guide the preclinical, CMC and clinical development of mRNA-1273 within the first 90 days of the contract. An original investigational new drug application (IND) will be filed with the United States Food and Drug Administration (FDA) to support the clinical development of the Moderna product from Phase 2 onwards.

IND Maintenance (WBS 1.5.1.2)
The Moderna-owned IND will be maintained to support the desired clinical development plan. As needed, meetings will be conducted to receive feedback and gain concurrence on the specifics of the development activities with the FDA.

BLA Submission (WBS 1.5.2.1)
Moderna will submit a Biologics License Application (BLA) and seek approval for the mRNA-1273 vaccine.

CMC (WBS 1.6)

CTM Manufacture for Phase 2 (WBS 1.6.3.2)
[***]

Process Development for Late Stage Clinical Supply (WBS 1.6.3.3)
mRNA Process Development
Technical Development will confirm and optimize the process parameters for mRNA manufacture. [***]\

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[***]

BLA Readiness (WBS 1.6.3.8)

In support of the Biologics License Application (BLA) due to the nature of the proposed timeline, it is likely that Moderna will need to complete some of process validation activities, primarily process characterization, after the completion of process performance qualification and before BLA filing. Moderna intends to rapidly develop a robust process for clinical manufacturing and PPQ, and then fully describe the acceptable design space for the process prior to BLA filing. Other activities to support this BLA filing, such as completing raw material qualification activities; if not included in the BLA submission, will require a supplement to the initial BLA. In the initial BLA filing Moderna will describe its control strategy to cover the gap between initial BLA filing and the BLA supplement.

Process Development for Full Commercial Scale (WBS 1.6.4.1)

The following section outlines the process development activities [***]. The goal of this work is to demonstrate the capability to produce mRNA-1273 at a scale that can support clinical demand.

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[***]

Stability Studies (WBS 1.6.5.4)

Throughout the program, many studies will be undertaken [***]. This includes studies using development bench scale material, engineering lot material, and GMP material. This body of data will be used to apply interim and long-term shelf life to the drug product and process intermediates.